

The Upper Functional G.I. Disorder

# The Pseudo-ulcer



## Ulcer-like symptoms: no G.I. pathology

The patient is convinced it's an ulcer. However, symptoms are not quite typical, and x-ray findings are negative. These findings and the results of additional diagnostic procedures exclude an organic basis for the patient's complaints. A diagnosis of "upper functional gastrointestinal disorder" is made, which is supported by the fact that episodes of painful symptoms coincide with episodes of excessive anxiety, as indicated by the history.

It may be useful to explain to the patient the mechanism by which emotions upset normal G.I. functioning, resulting in hypersecretion and hypermotility and thus causing such symptoms as nausea and epigastric pain. In upper functional gastrointestinal disorders, counseling by the primary physician can often help the patient to understand how excessive anxiety may cause flare-ups of G.I. symptoms.

A disproportionate number of patients seen by the general practitioner suffer from functional disorders, as do more than half of those seen by the gastroenterologist. Where milder cases may respond to counsel-

ing alone, if symptoms are severe and disabling to any degree, a suitable regimen may include medication to reduce the symptoms and the excessive anxiety that often provokes these distressing symptoms.

In these cases, Librax as an adjunct can greatly contribute to the course of therapy. Its dual action can offer relief of both painful symptoms and excessive anxiety, because each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cimetidine HCl. The anxiolytic action of Librax® (chloridazepoxide HCl) makes Librax exceptional among drugs for certain gastrointestinal

disorders associated with excessive anxiety; the cimetidine (Tagamet) component furnishes independent antireflux, antispasmodic action. Dosage is flexible; it may be adjusted according to your patient's requirements within the range of 1 or 2 capsules three or four times daily, up to 8 capsules daily in divided doses.

\*Rome R.P., Bannick T.T.: Orientation and mechanism of functional disorders: clinical pharmacologic correlation, chap. 133, in *Gastroenterology*, edited by Becker H.L., Philadelphia, J.B. Saunders Company, 1968, p. 1116

An adjunct in anxiety-related upper functional G.I. disorders

### Librax®

Each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cimetidine HCl.

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Symptomatic relief of hypersecretion, hypermotility and anxiety and tension states associated with organic or functional gastrointestinal disorders; and as adjunctive therapy in the management of peptic ulcer, gastritis, duodenitis, irritable bowel syndrome, spastic colitis, and mild ulcerative colitis.

**Contraindications:** Patients with glaucoma, prostatic hyperplasia and benign bladder neck obstruction; known hypersensitivity to chloridazepoxide hydrochloride and/or cimetidine hydrochloride.

**Warnings:** Caution patients about possible combined effects with alcohol and other CNS depressants. As with all CNS-acting drugs, caution patients against hazardous occupations requiring complete mental alertness (e.g., operating machinery). Though physical and psychological dependence have rarely been reported on recommended doses, use caution in known addiction-prone individuals or those who might increase dosage; withdrawal symptoms (including convulsions) following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in

pregnancy, lactation, or in women of childbearing age requires that its potential benefits be weighed against its long effect on lactation may occur. **Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude development of ataxia, drowsiness or confusion (not more than two capsules per day initially; increase gradually as needed and tolerated). Though generally not recommended, if combination therapy with other psychotropics seems indicated, carefully consider individual pharmacologic effects, particularly in use of potential drugs such as MAO inhibitors and phenothiazines. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions of impaired renal or hepatic function and acute rage have been reported in psychiatric patients. Employ usual precautions in treatment of anxiety states with evidence of impending depression; suicidal tendency may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulants; causal relationship has not been established clinically. **Adverse Reactions:** No side effects or manifestations not seen with either compound alone have been reported with Librax. When chloridazepoxide hydrochloride is used alone, drowsi-

ness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment, but are also occasionally observed at the lower dosage ranges. In a few instances symptoms have been reported, also encountered are isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased libido—all infrequent and generally controlled with dosage reduction; changes in ECG patients dose-volume (but activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally with chloridazepoxide hydrochloride, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax are typical of anticholinergic agents, i.e., dryness of mouth, blurring of vision, urinary hesitancy and constipation. Constipation has occurred most often when Librax therapy is combined with other antispasmodics and/or laxative diets.



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Med Trib

# Medical Tribune

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and Medical News—

Wednesday, February 5, 1975

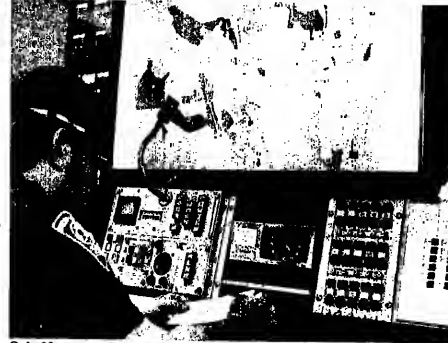


**ARTIFICIAL BETA CELL** now being developed at USC has reached stage where unit's tiny glucose sensor can monitor blood of patients in diabetic crises. Dr. Samuel P. Beasman reports next step will be control with extracorporeal use of 5-part unit — a sensor plus computer to translate signal, micro-pump, power supply, insulin reservoir. Once computer is programmed for individual patient, Calif. group plans implantation of miniaturized unit. Dr. Beasman thinks diabetic may need only 10 u. or less of insulin daily if hormone can be emitted in right amounts at stress times.

**NRI FUNDING** — Increased tobacco and alcohol taxes, variations on the tax-credit idea, revisions on other types of excise taxes, and a value-added tax are all being studied as possible sources of revenue for a national health insurance program, Rep. Al Ullman, Acting Comm. of House Ways & Means told *MT*. Rep. Ullman has said he does not favor further extensions of the payroll tax.

**NO NRI IN '75?** — "Even if legislation were proposed this year, it would be 1977 at the earliest before national health insurance is implemented," a Congressional staffer told *MT*.

## Emergency System at Work Saving Lives



Only 20 percent of the country has been able to afford the centralized emergency phone system, as in New Haven, above. Yet at least half of all heart attack and accident victims die before they reach the hospital as a result of failures in communications and transportation.

## New US Role Is a Bright Spot In 'Bleak' Car Deaths Picture

By LINDA MURRAY  
*Special Tribune Correspondent*

Although deaths from traffic accidents were down last year—an impressive 18 per cent drop for the first 11 months of '74—the credit goes to the slackened 55-mile speed limit, rather

Part I

than any strides in the development of emergency medical services. "For most of the country," confirms Dr. David R. Boyd, former chief of the Illinois Division of EMS and now director of HEW's Division of EMS, "the picture is still pretty bleak."

In 1972, more than 115,000 people

died, 400,000 more were permanently disabled, and the loss to the economy was estimated at over \$28 billion. The average American community suffers only about one in 20 trauma victims to their former lifestyle.

But now there are some signs that things may take a turn for the better, even in rural and wilderness areas.

Most significant is the new leadership role assumed by the federal government under the Emergency Medical Services Systems Act of 1973, which designates HEW's Division of EMS as the lead agency, responsible for coordinating all federal activity and spending \$185 million over a three year

Continued on page 21

## Nader Says Doctors Slight Key Mission of Prevention

By FRANCES GOODNIGHT  
*Medical Tribune Staff*

**NEW YORK**—Consumer advocate Ralph Nader took an appraising look here at the nation's medical profession and described its concerns and activities as "heavily deployed" in the area of after-the-fact disease and trauma, with far too little emphasis on their prevention.

"The primary mission in medicine is prevention and preservation," Mr. Nader declared during an Honors Program Lecture given at the New York University School of Medicine.

Yet in his view the profession has not extended resources or even much support to preventive medicine. Medical schools "do not teach it extensively," and physicians who choose to specialize in it "are not considered high—if anywhere—on the status pole."

This doesn't mean, Mr. Nader said, that efforts by individual doctors have been lacking. Citing the auto safety movement, the lawyer pointed out that its basic inspiration came from medical journal articles of the 1930s and

Continued on page 25

## Serum Hepatitis Prophylaxis Tested



The effectiveness of anti-HB Ag immunoglobulin in preventing serum hepatitis of accidentally exposed hospital personnel is being tested in Britain and the United States. Story, page 2.

## Anti-HB Ag Immunoglobulin Staves Off Clinical Hepatitis B

By JAMES MAGEE  
Medical Tribune Staff

MILAN, ITALY—A British team has reported successful prevention of the appearance of clinical hepatitis B following accidental inoculations with antigen bearing material, through prophylactic use of anti-HB Ag immunoglobulin.

Reporting the first results of an uncontrolled Medical Research Council trial involving 110 persons with inoculation injuries, Dr. Sheila Polakov said the average interval from accident to prophylaxis was six days. More than 80 per cent of the participants were given prophylaxis within eight days of the accident. The trial began in September 1973.

### 2 of 61 Develop Jaundice

Accidents included transfusion of blood or blood products, penetration of the skin, contamination of the conjunctival sac or cuts or abrasions of the skin involving material containing HB Ag, whether blood, other body fluids, or laboratory reagents, she told a symposium on viral hepatitis at the International Association of Biological Standardization meeting here.

Of 61 study participants whose accidents involved penetration, and who were followed, to date two have developed jaundice with hepatitis B antigenemia. In one the illness began 17 weeks after the accident. The attack was mild and the antigenemia transient; the patient made a full clinical recovery within five weeks of the onset.

The first indication of illness in the other was detection of HB Ag and raised aminotransferase levels in a follow-up sample taken 18 weeks after the accident; jaundice and other manifestations developed shortly afterwards. The attack was recent and the course of the illness is still being monitored.

### 4 Globulin Studies On In US

Currently, four double-blind studies are underway in the United States to test the efficacy of hyperimmune globulin in preventing clinical hepatitis B.

[Three of these studies are under the direction of the National Heart and Lung Institute's Division of Blood Diseases and Resources, including trials of the globulin in renal dialysis patients, patients with needle stick and other accidental exposure, and transfused patients. The VA also has a double-blind study underway.]

Dr. Harvey G. Klein, project officer for the NHLI studies, noted that if early results indicate the hyperimmune globulin is effective, a Data Safety Monitoring Committee headed by Douglas M. Surgeon, Ph.D., former dean of the State University of New York's Buffalo School of Medicine, will halt the study and release the data.

Dr. Polakov, who is associated with the epidemiological research laboratory, Central Public Health Laboratory, London, explained that when an accident that meets the study criteria is reported a sample of the inoculated material is tested for HB Ag. If a sample is not available, documentary

evidence of the presence of HB Ag by previous tests of the material or, if the source is a person, of samples taken at any time in the four weeks before the accident, is accepted.

A serum sample, taken from the person who sustained the accident, is also tested by routine methods for HB Ag and anti-HB Ag. If the results of these tests are negative and the immunoglobulin can be administered within approximately two weeks of the accident, the subject is enrolled in the study. A 500 mg. dose of the material is given intramuscularly and the subject is observed for any immediate reactions.

Each subject is followed-up for one year after the accident. Serum samples are taken, usually at four weekly intervals in the first six months; two further samples are taken, one at nine months and the other at or about one year after the accident.

In the first year of study 110 persons were enrolled. Most of the participants were nursing, medical or laboratory staff; two were patients who had been infused with a blood product later found to be contaminated. Of the 110 accidents, penetration of

the skin accounted for more than half. There was no evidence of infection among subjects who contaminated abrasions or ingested infected material.

### Anti-HB Ag Detected In 3

None of the participants appears to have developed asymptomatic HB Ag carriage, but anti-HB Ag was detected by counterimmunoelectrophoresis in sera from three, who had no other evidence of infection, at 18, 20 and 23 weeks after the accidents. In one case anti-HB Ag was transitory; in another it is still present 20 weeks after it was first detected; in the third case it was detected in the most recent specimen. Four subjects each had a notably raised aminotransferase level in one follow-up specimen—one of 14 weeks, two at approximately 20 weeks and one at 27 weeks after the accident; none of the four had any other evidence of infection.

"These are of course preliminary results; further laboratory tests which will be made at the end of the study may reveal evidence of infection that could not be detected by the test methods in routine use," Dr. Polakov concluded.

Co-author was Dr. W. D. A. Maycock, The Lister Institute of Preventive Medicine, Elstree, Herts, United Kingdom.

## Lessons Gang Agley



"Something specific to the alcohol molecule" causes addicted mice to forget well-learned lessons, according to Dr. Gerhard Freund (shown with intoxicated mouse), of University of Florida.

## Laparoscopy 'Best' of 4 Sterilization Routes

Medical Tribune World Service

BURNOE AIRS—Laparoscopy appears to be superior to colposcopy, culdoscopy, or laparotomy for sterilization of women who have not recently been pregnant, according to a study by the International Fertility Research Program (IFRP).

Complications of the four procedures during surgery and in the first to eighth postoperative weeks were reported at the Eighth World Congress on Fertility and Sterility by Dr. William E. Brenner and David A. Edelman, Ph.D.

They evaluated the results of 401 culdoscopies, 799 colposcopies, 482 laparoscopies, and 279 laparotomies performed at 11 American institutions from October, 1972, to December, 1973.

The most common operative difficulty with endoscopic methods was inadequate visualization of the uterus. This occurred in 3.5 per cent of culdoscopies and 2.5 per cent of laparoscopies.

Blood loss greater than 100 ml was more common with both vaginal methods.

Postoperative pelvic infections were more frequent with the vaginal methods—6 per cent with culdoscopy and 4.5 per cent with colposcopy.

Incisional complications were more common with the abdominal approaches.

Operative and hospitalization times were significantly shorter with the endoscopic methods, and the proportion of women resuming normal activities within four weeks of sterilization was higher.

While technical difficulties, operative complications, surgical and hospitalization times, and resumption of activities were similar with laparosc-

copy and culdoscopy, pelvic infection was more common with culdoscopy. Dr. Brenner is director of IFRP research and training and Associate Professor at the University of North Carolina. Dr. Edelman is on the staff of the University of North Carolina.

### Treatment of Sterility

A Japanese physician reported that of 100 sterile women treated with domiphen citrate, ovulation was induced in 84 and 39 became pregnant.

Dr. Taro Shimomura, of Kitano Hospital, Osaka, said that the patients included 65 with primary sterility. Thirteen of the 100 patients complained of infrequent ovulation; 26, anovulatory menstruation; 55, first-grade amenorrhea, which responded to progesterone, with bleeding; and six,

secondary amenorrhea, which responded to estrogen-progesterone, with bleeding.

Domiphen citrate was given on the fifth day of menses following either spontaneous or induced bleeding. The initial dose was 50 mg. in one tablet for five days. When ovulation was induced, the drug was not given in the next cycle, and carryover effects were observed.

When ovulation was not induced in the observed cycle, 50 mg. of the agent was given daily for five days after induced bleeding.

When ovulation was not induced in the first cycle, the dosage was increased to 100 mg. daily for five days in the next period.

Co-worker in the study was Dr. Michio Kitagawa.

## Thin Fiberscope Facilitates Studies Of Esophagus, Stomach, Duodenum

Medical Tribune World Service

MEXICO CITY—In endoscopic examination of the esophagus, stomach, and duodenum, a fiberscope that is about half the standard size has shown significant advantages. It was reported at the Third International Congress of Gastrointestinal Endoscopy.

This instrument, Olympus GIF-P, with a tube diameter of 6.8 mm can be passed with little premedication. It was originally developed for esophageal cancer surveying in Japan, and has been widely employed there. Initially, it was brought to the United States for pediatric endoscopy.

"However," said Dr. J. F. Morrissey, Professor of Medicine at the University of Wisconsin, "there was very little interest shown in endoscopy on the part of U.S. pediatricians. We took it up

in adults a little over a year ago and now have what I believe to be the only series so far reported."

On the basis of experience in more than 100 patients, the instrument was found to be preferable for the examination of patients with severe cardiac or pulmonary disease, those who must be examined in bed, and those who are extremely apprehensive or otherwise intolerant to examination with the normal-size endoscope.

Also, Dr. Morrissey said, it has been found useful for following healing in patients with esophagitis, erosive gastritis, and gastric or duodenal ulceration, and for observing effects of drugs in peptic ulcer healing.

The instrument is of special value in the examination of patients with esophageal or pyloric narrowing

Wednesday, February 5, 1973

## Cool-Off Drive In Israel May Hit Top MDs

Medical Tribune World Service

TEL AVIV—Some of Israel's outstanding physicians may be coming victims of the Government's drive to "cool off an overheated economy."

One way has been to take money out of circulation by cracking down on income-tax evaders, and a well-known physician at the Hadassah Medical Center, Jerusalem, has become the first to be tackled in this effort.

Another way has been to crack down on private practice. Although "socialized medicine" exists in theory in Israel, a few hospital department heads have been quietly allowed to practice privately in their homes and private offices. This applied equally to Government, Kupat Holim (Sick Fund), and public hospitals. The reason was that the highest-paid staff doctor in a hospital in Israel rarely has take-home pay of more than 2,000 Israeli pounds (about \$332)—less than that of most skilled laborers.

### Privileges for Top Doctors

To keep outstanding physicians, as well as others, from emigrating from Israel, they were granted various tax benefits, such as air allowances, telephone allowances, and professional literature allowances.

Moreover, it was tacitly agreed to allow such physicians to practice privately and to admit their patients to their hospitals out of turn and without hospital charges in most cases. (Since most Israelis are members of Kupat Holim, the question of hospital fees rarely arose.)

Many other physicians, who never received such sanction, followed the same practice, with the heads of the various health networks turning a blind eye.

This "official blindness" went on for years, although it was well known that the "private practice" of some of these doctors consisted of nothing more than a superficial examination in the doctor's private office with the understanding that the patient would be admitted the next day to the hospital without having to face a long line and an impartial admissions doctor.

### Few Give Receipts

Few Israeli physicians give receipts for treatment rendered in their private offices. Due to high marginal taxes, which would gobble up two-thirds to three-quarters of the fee, it would not be worthwhile to practice privately if income taxes were paid.

Therefore, many department heads have had an unwritten but clearly understood law: a certain fee to cash without a receipt, or three times that amount if a receipt is given.

The practice has been so widespread, especially in Kupat Holim, that its director-general, Asher Yedlin, recently said, "We are willing to pay each department head 50 per cent above his present take-home pay if he would give up his private practice."

## Treatment Instead of Jail



Under a new law in Florida, a person may no longer be arrested for public drunkenness. Instead, he may be driven home or taken to a treatment center, as above, where he will be checked in and given a physical exam, a shower, and a bed.

### Israeli Life Expectancy Up

Medical Tribune World Service

TEL AVIV—Life expectancy of Israeli males rose from 69.8 years in 1970 to 70.7 in 1973, and of females from 70.3 years in 1970 to 73.6 in 1973; infant mortality fell from 24.2 per thousand in 1972 to 22.8 per thousand in 1973. Dr. Avraham Atzman, a public health specialist, announced recently.

Dr. Atzman also noted that the number of Israelis 65 years old or more, had increased from 3.9 per cent of the population in 1948 to 5.4 per cent in 1964, and to 7.9 per cent in 1973.

## DMT Found in Man, May Be Key to Some Schizophrenia

Medical Tribune World Service

MELBOURNE—The manufacture of an LSD-type drug in the brain may be the key to the cause of several mental illnesses, Dr. John Smythies, Professor of Psychiatry at the University of Alabama, told an international symposium on schizophrenia here.

The powerful hallucinogen dimethyltryptamine (DMT), thought previously to exist in plant life only, has been found in man, he said.

Research has indicated there may be more DMT in schizophrenics than in normal people, Dr. Smythies said. DMT was converted from brain tryptamine, by enzyme action, he said.

If its incrimination in schizophrenia is substantiated, therapy designed to limit the amount of the enzyme causing production of the DMT might be developed, he observed.

### Birth Month Factor

A Melbourne psychiatrist presented survey results supporting the hypothesis that date of birth may be a factor in development of schizophrenia.

Dr. Ivor H. Jones, first assistant in Melbourne University's Department of Psychiatry, reported that a survey

## Tests Support Argon Laser For GI Lesions

Medical Tribune World Service

MEXICO CITY—Initial trials in animals and fresh autopsy material by West German investigators indicated that the argon laser beam may be superior to electrocoagulation in the treatment of certain lesions of the gastrointestinal tract.

"I have to say 'may be,'" Dr. Peter Frühlmorgen, of the University of Erlangen-Nuremberg, told the Third International Congress of Gastrointestinal Endoscopy here, "because our results up to now are based on acute experiments. We have only recently started chronic experiments with a flexible laser carrier."

### New Avenues of Application

"Keeping in mind that effects in the cat intestine or in dead human tissue cannot be extrapolated to live human tissue pulsing with blood," it nevertheless appears evident that new avenues of application of photocoagulation within the framework of gastroenterologic endoscopy have been opened for the treatment not only of varices, hemangiomas, and bleeding lesions but also for the possible destruction of benign and malignant tumors."

The argon-laser beam produced tissue reactions of edema, coagulation, and charring in the gastrointestinal tract with a selective effect on tissues from its various parts, Dr. Frühlmorgen said.

Tissue reaction was found to be dependent upon the power of the beam applied and the duration of application with maximum coagulation in the therapeutic range taking place in the submucosa.

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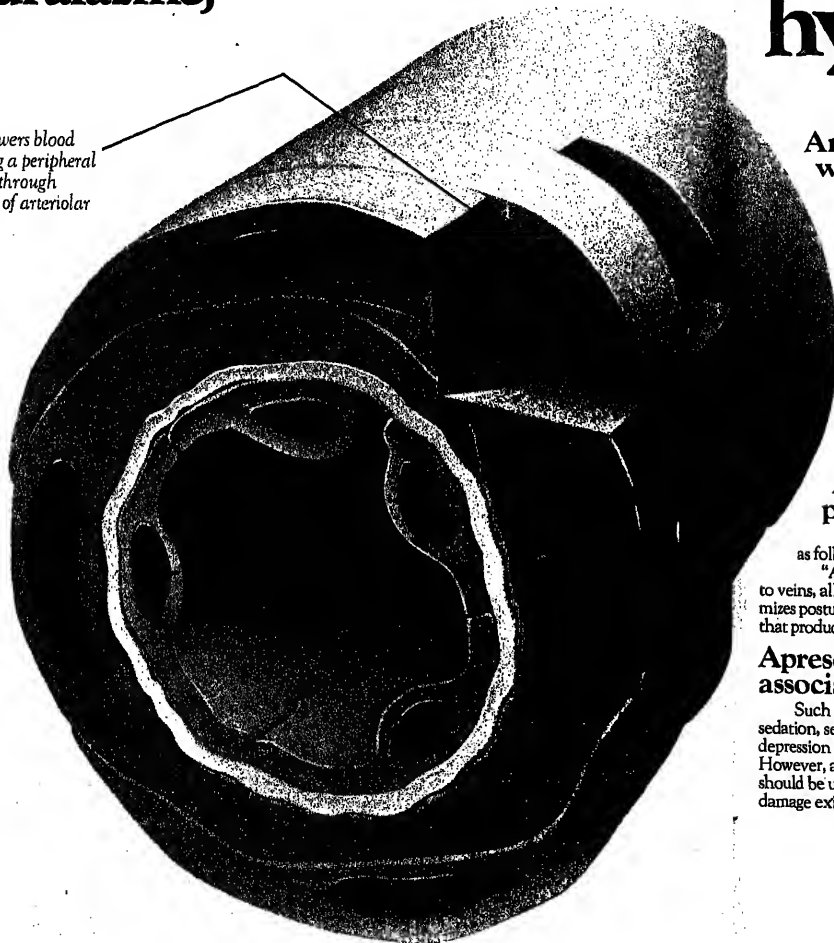
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# Apresoline®...where the action is in treating (hydralazine) hypertension

Apresoline lowers blood pressure by exerting a peripheral vasodilating effect through a direct relaxation of arteriolar smooth muscle.



## An antihypertensive idea whose time has come

Doctors who treat hypertension are increasingly interested in the one oral drug that has a mechanism of action exclusively its own—Apresoline.

Apresoline is in an antihypertensive class by itself because it reduces blood pressure through a unique mechanism. Acting at the ultimate site of hypertension, it directly relaxes arteriolar smooth muscle to decrease peripheral vascular resistance and arterial pressure. As blood pressure falls, there is an accompanying rise in cardiac output and rate.

Apresoline also maintains or increases renal and cerebral blood flow,

## Apresoline minimizes postural hypotension

Nickerson<sup>1</sup> describes the action of Apresoline as follows:

"A preferential effect on arterioles, as compared to veins, allows the increase in cardiac output and minimizes postural hypotension; the latter is much less than that produced by agents blocking sympathetic nerves."

## Apresoline avoids side effects associated with other agents

Such untoward reactions as drowsiness, lethargy, sedation, sexual dysfunction, and exacerbation of mental depression are not usually encountered with Apresoline. However, as with any antihypertensive agent, hydralazine should be used with caution where advanced renal damage exists.

## Apresoline helps tailor the regimen to the patient

When Apresoline is added to an existing antihypertensive regimen, it introduces a different and complementary pharmacologic approach to the control of your patient's hypertension.

Apresoline thus affords the physician a variety of combinations with which he can construct regimens more closely molded to individual requirements. According to Freis<sup>8</sup>, such a combination of drugs, each with a different antihypertensive mechanism, is the most effective way to control blood pressure. This may also permit lower drug dosages.

Apresoline lends itself admirably to the contemporary antihypertensive rationale and its therapeutic goals: more vigorous and more effective control of blood pressure through a plurality of mechanisms.

### Apresoline: used effectively in the VA studies

Apresoline was one of the three basic drugs used in two published VA cooperative studies.<sup>9,11</sup>

**References** 1. Nickerson M: Antihypertensive agents and the drug therapy of hypertension. In Goodman LS, Gilman A (eds): *The Pharmacological Basis of Therapeutics*, 8th ed. New York: Macmillan Company, 1970, p 723. 2. Freid ED: Hypertension: a controllable disease. *Clin Pharmacol Ther* 13:627-632, 1972. 3. Effects of treatment on morbidity in hypertension: Results in patients with diastolic blood pressures averaging 115 through 129 mm Hg. Veterans Administration Cooperative Study Group on Antihypertensive Agents. *JAMA* 202:1028-1034, 1967. 4. Effects of treatment on morbidity in persons with 170 mm in patients with 160 through 179 mm diastolic pressure averaging 100 through 114 mm Hg. Veterans Administration Cooperative Study Group on Antihypertensive Agents. *JAMA* 213:1149-1152, 1970.

**Apresoline®** hydrochloride  
(hydralazine hydrochloride)

## TABLETS

**TABLETS**  
**INDICATIONS**  
Essential hypertension, alone or as an adjunct.  
**CONTRAINDICATIONS**  
Hypersensitivity; coronary artery disease; mitral  
valvular rheumatic heart disease.  
**WARNINGS**  
Chronic administration of doses over 400 mg per  
day may produce an arthritis-like syndrome lead-

ing to a clinical picture simulating acute systemic lupus erythematosus. This may also occur at lower doses. Most of these reactions are reversible with low levels of therapy, but long-term treatment with steroids may be necessary and residual effects have been detected many years later. Complete blood counts, E.C. cell preparations and anti-nuclear antibody titer determinations are indicated before and periodically during prolonged therapy, even though patients are asymptomatic. These studies are also indicated in the presence of any unexplained symptoms.

Use MAO inhibitors with caution.

### Usage in Pregnancy

The drug should be used only when, in the judgment of the physician, it is deemed essential to the welfare of the patient.

**PRECAUTIONS**  
Use cautiously in

other cardiovascular diseases, cerebral vascular accidents, and advanced renal damage. Postural hypotension may occur, and the pressor response to epinephrine may be reduced. Peripheral neuritis, evidenced by paresthesias, numbness, and tingling, has been observed. Published evidence suggests an antihypertensive effect.

and addition of pyridoxine to the regimen if symptoms develop. Blood dyscrasias, consisting of reduction in hemoglobin and red cell count, leukopenia, agranulocytosis, and purpura, have been reported rarely. If such abnormalities develop, discontinue therapy. Periodic blood counts are advised during prolonged therapy.

**ADVERSE REACTIONS**  
**Common:** Headache, palpitations, anorexia, nausea, vomiting, diarrhea, tachycardia, angina pectoris. Less frequent: Vaginal cramping, flushing.

evidenced by paresthesias, numbness, and tingling; edema; dizziness; tremors; muscle cramps; psychotic reactions characterized by depression, disorientation, or anxiety; hyperreflexivity, including rash, urticaria, pruritus, fever, chills, arthralgia, eosinophilia, and, rarely, hepatitis; constipation; difficulty in micturition; dyspnea; paralytic ileus; lymphadenopathy; splenomegaly; blood dyscrasias; consistent reduction in hemoglobin; and, rarely, capillary leukopenia, granulocytosis, and purpura; hypotension; paradoxical pressor response.

**DOSAD**  
Initiate

edual according to individual response. Start with 10 mg 4 times daily for the first 2 to 4 days, increase to 25 mg 4 times daily for balance of first week. For second and subsequent weeks, increase dosage to 50 mg 4 times daily. For maintenance, adjust dosage to keep blood effective level.

The incidence of toxic effects, particularly the L.E. cell syndrome, is high in this group of patients receiving large doses of Aprosoline.

In a few resistant patients, up to 300 mg Aprosoline daily may be required for a significant antihyper-

tensive effect. In such cases, a lower dosage of Acetaminophen combined with a thiazide, reserpine, or both may be considered. However, when combining therapy, individual titration is essential to insure the lowest possible therapeutic dose of each drug.

**HOW SUPPLIED**

Tablets, 10 mg (pale yellow, dry-coated); bottles of 100 and 1000.

Tablets, 25 mg (deep blue, dry-coated); bottles of 100 and 1000.

Tablets, 50 mg (lilac, dry-coated); bottles of 100, 500, and 1000.

Tablets, 100 mg (peach, dry-coated); bottles of 100.  
Consult complete literature before prescribing.  
CIBA Pharmaceutical Company  
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**C I B A**

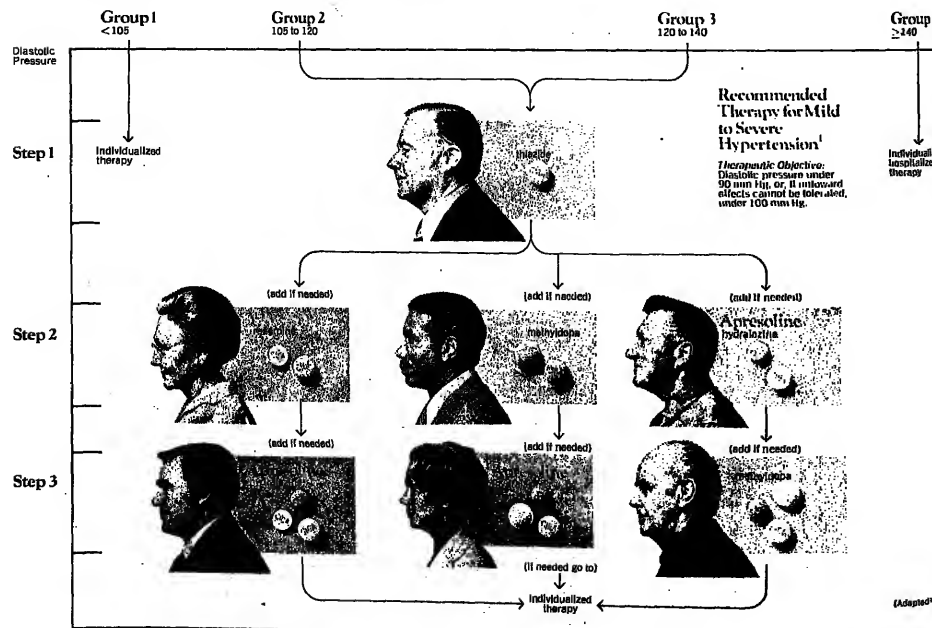
# Apresoline... (hydralazine) part of the Hypertension Task Force "plan of action"

In September 1973, Task Force I of the National High Blood Pressure Education Program recommended a series of antihypertensive regimens for groups with hypertension ranging from mild to severe. Hydralazine—used in combination with sympathetic-inhibiting and/or diuretic antihypertensive

agents—was a specific recommendation for "second step" and "third step" therapy in patients with diastolic pressures ranging from 105 to 140 mm Hg. Hydralazine played a prominent role in the Task Force regimens because of its compatibility with almost any antihypertensive regimen. For

Apresoline can be combined advantageously with nearly all diuretics and sympathetic inhibitors.

Reference: 1. Report of Task Force I, National High Blood Pressure Education Program. Recommendations for a National High Blood Pressure Program. *Annals of the New York Academy of Sciences*, Sept. 1, 1973. (NIH) 74-595.



Apresoline® (hydralazine)  
...acts directly at the ultimate  
site of hypertension  
...brings something  
special to almost any  
antihypertensive  
regimen

For brief prescribing information,  
please see preceding pages.



C I B A

Wednesday, February 5, 1975

MEDICAL TRIBUNE

## Check, Double Check Breast Ritual 'Still Best'

Medical Tribune Report

BOSTON—A combination of self-examination and twice-a-year checkups by a physician is still the most effective method for the early detection of breast cancer, Dr. Richard Wilson told a Harvard Medical Society symposium here.

"I'm afraid this somewhat quaint ritual is here to stay until we have a no-fail test, such as a blood test," he said.

Dr. Wilson, who is Associate Professor of Surgery at the Peter Bent Brigham Hospital, pointed out that although xeroradiography and thermography are effective for early diagnosis in patients who are at risk because of their age, they have not proved their worth when used for the younger woman.

"There is a great danger today to put too much faith in these techniques," Dr. Wilson warned the audience of students and physicians.

He reminded them that there is a great deal of fibrocystic disease in most breasts and that the breasts change constantly through the monthly cycle.

"The real job is to decide that what you detect is a matter of concern," he remarked.

### More Aspirations in Office

Dr. Wilson said that he is doing "more cystic aspirations in my office than ever before; otherwise I biopsy all mass lesions—regardless of what the screening says."

Dr. Lester Kalisher said that while xeroradiography can reveal a cancerous or precancerous lesion before it becomes palpable, the barely palpable 2-cm. mass today is considered a late symptom.

At the Massachusetts General Hospital, where he is an instructor in Radiology, xeroradiography is used in women who present symptoms or are considered to be at high risk because of family history, age, or earlier lesions.

"What we look for are the microcalcifications without mass," Dr. Kalisher said. "Eighty per cent of these malignancies have such calcification."

Physicians at M.G.H., he added, also look for asymmetric duct patterns—unusual duct outlines that appear on one side of the breast and not on the other, and are easy to spot by xeroradiography because both sides are presented at the same time.

Of the 1,315 referrals for xeroradiography made at the hospital so far, he reported, 125 were recommended

for biopsy. Sixty-four of the lesions proved malignant, 33 benign, and the rest were not biopsied.

Dr. Norman L. Sadowsky, radiologist in chief at the Faulkner Hospital, said that thermography is the preferred diagnostic tool at his institution.

Thermography picks up some carcinomas that xeroradiography does not, he said, and further, the method is more practical for annual examinations. It takes little time—about 10 minutes—and is so inexpensive to use that Faulkner does not charge for it.

Charges for a xeroradiography examination in Boston, it was noted, range from \$50 to \$100.

Initial costs for installation also differ considerably, although in the other direction, the seminar was told. The

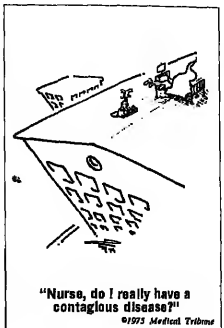
thermography unit at Faulkner cost approximately \$35,000, whereas the staff at M.G.H. put together a xeroradiography facility for \$5,000, using mostly second-hand equipment.

### Cancer Exams Required

Medical Tribune World Service

SOFIA, BULGARIA — Examinations for cancer, including a cytological checkup, are obligatory every second year for all Bulgarian women, starting this year.

In the past three years nearly half of all women over 30 have been examined, resulting in four times as many diagnoses of cancer as in the previous period and eight times as many patients identified with cancer in its very early stages.



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## Sex Hormone Combo Proposed for Male Pill

Medical Tribune World Service

MELBOURNE—Dr. Michael Briggs, director of biochemistry at the Alfred Hospital, and Dr. Maxine Briggs, assistant medical superintendent, said that a combination estrogen-androgen could be the answer to the search for a safe and effective male contraceptive pill free of the side effects of loss of libido and testicular atrophy.

Dr. Michael Briggs related that he became interested in this approach when he discovered that two elderly osteoporosis patients who were taking an estrogen-androgen combination developed severely reduced sperm production.

Then, five healthy volunteers were selected and a trial started with two

pills being taken daily at meals. By day 63 of hormone treatment, four of the five men had become aspermic, and during the 18th week, the fifth patient also became aspermic.

### No Pregnancies in 16 Weeks

The treatment was discontinued for 34 weeks and the volunteers' wives went off their oral contraceptives from week 18. No pregnancies resulted in the 16 trial weeks. Sperm production was back to normal within five weeks after discontinuation of hormone treatment.

As a control for questions on sex drive, the volunteers were given placebo tablets for three weeks at the start of the course.

Two volunteers reported decreased libido in the first eight weeks, which included the placebo period, but normal libido for the remainder of the study.

Another man reported increased libido during the second half of the treatment period, while he and another subject experienced a reduction in libido after treatment was stopped.

Three men reported occasional mild nausea while they were taking the pill. Dr. Briggs said there were no changes in skin, hair, breasts, or urination.

With further refinement, he said, the pill could be developed to be taken less frequently—every other day or a few times every two weeks.



... brief summaries of editorially comments in current medical and scientific journals.

### Disaster Management

... if a fully loaded aircraft flying over a city should crash on a residential area or in the city center, it could produce a casualty list approaching five thousand. Such a disaster would require the help of the armed forces and their medical services. Thought must also be given to the possibility of nuclear disaster. This is again an area where there is very little experience, but every hospital should have some idea how it would cope with decontamination after nuclear fall-out—largely a matter of providing a special area with a plentiful supply of water. (Special article, David Caro; The Lancet 2:1309, Nov. 30, 1974)

### Delay in Energy Sources

"Consumption of energy goes on unabated in spite of a recession, higher prices, and presidential appeals. But domestic reserves of hydrocarbons are being depleted rapidly and the stage is being set for empty gasoline pumps, cold homes, and large-scale unemployment unless there is a drastic change in attitudes soon. A major factor is the long time span involved in creating new sources of energy."

"The first sentence went critical in December 1942. In 1973, nuclear energy accounted for only 1 percent of the nation's energy consumption. Ten years from now, nuclear energy will meet at most 7 percent of the nation's needs."

"Thus, for at least the next decade, energy horizons will be limited by oil, natural gas, and coal. But available domestic supplies of oil and gas are diminishing at the rate of 4 to 6 percent per year for oil and about 7 to 8 percent per year for natural gas."

"Perhaps the most serious and certainly the least recognized problems lie in the supplies of natural gas. It heats 55 percent of the nation's homes, is widely used as a feedstock for petrochemicals, including fertilizer, and is by far the largest source of energy for industry... equivalent to that of about 5 million barrels of oil. National policy accords priority to residential demand for natural gas. The rate of decay of supplies is such that by 1980, with a few exceptions, industry will be prevented from using natural gas. This would have enormous effects on the economy."

"To make good the energy deficit due to decay of natural gas alone, a doubling of coal production during the next 6 years would be required. But to open a new underground mine requires about 5 years. The quickest path toward relief is expansion of surface mining of low-sulfur coal in the Rocky Mountain States. But with various delays connected with changeovers from gas to oil to coal and with environmental considerations, heaven only knows when the country will emerge from the years of travel and discontent that it is now entering." (Editorial, Philip H. Abelson, Science 187:17, Jan. 10, 1975)

## Blunt Chest Trauma Cited As Cause of Pneumatoceles

Medical Tribune Report

GALVESTON, TEX.—Traumatic lung and paramechastical pneumatoceles are "not well appreciated" as a manifestation of nonpenetrating chest trauma, according to a radiologist at the University of Texas Medical Branch.

These lesions are "definite, acutely formed, primary structural manifestations" of injury, and not secondary lesions—that is, they do not result from the resolution of a pulmonary hematoma—according to Dr. Charles J. Fagan, Associate Professor of Radiology.

"Awareness of this fact," he said, "will explain the [common] finding of a cyst, often containing an air-fluid level, on the initial or emergency room roentgenogram" of patients who have suffered nonpenetrating chest trauma, most commonly from an automobile accident.

Hemoptysis frequently follows the accident and may be seen during the initial physical examination of the patient, he noted.

In general, Dr. Fagan said, patients are asymptomatic, and the pneumatoceles eventually disappear with no treatment; they last from about one week to as long as three months.

The roentgenographic appearance of the traumatic pneumatocele varies according to its location, whether it holds blood, and whether it is associated with a pulmonary contusion, he observed.

It may be completely encapsulated and appear as a solitary pulmonary nodule, like that of a hemangioma, he said, but

more commonly, the traumatic lung cyst is represented by an isolated air-fluid level in the lung parenchyma, and the actual margin of the pneumatocele, which is composed of compressed or contused lung parenchyma, is either imperceptible or quite thin.

The pneumatocele, he added, may be obscured if the associated pulmonary contusion is extensive. It can be observed "with or without air-fluid level" about three to six days later, after the contusion has been resolved.

Dr. Fagan also noted that an injury on the left side of the chest may produce a pneumatocele on the right, and an injury to the anterior wall a pneumatocele in the posterior.

## New Japanese Audiovisual Teaching Aid



A Japanese medical student uses one of the new audiovisual units for teaching x-ray diagnosis developed by the Japan Research Center. She pushes a button to turn on a physician discussion of the x-ray she is studying.

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Now, for both aspects of constipation



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Provides a unique natural laxative—standardized senna concentrate... virtually colon-specific... effectiveness documented in numerous published studies comprising thousands of patients.

Provides a classic stool softener—DSS... complementing the laxative action by softening the stool for smoother and easier passage.

Comfortable, predictable evacuation... a bedtime dose of SENOKOT S Tablets usually induces comfortable evacuation the next morning, allowing uninterrupted sleep. SENOKOT S Tablets aid in rehabilitation of the constipated patient by facilitating regular elimination.

Indications: SENOKOT S Tablets offer welcome relief in functional constipation when combined with proper fluid intake and a high-fiber diet. Indicated especially for the aged, postpartum, hemorrhoids, dosage (preferably at bedtime). Adults: 1 to 2 tablets daily. Maximum dose: 4 tablets daily. Children (above 6 years): 1 tablet daily. For severe constipation, the individual requires a dose of 2 tablets daily. SENOKOT S Tablets are not habit-forming. Do not use if you are taking other laxatives.

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## Induced Abortions Reported To Boost Risk of Spontaneous

Medical Tribune World Service

PRAGUE — Artificial termination of pregnancy greatly increases the risk of a subsequent spontaneous abortion, Prof. Alfred Kotásek, head of the Gynecological and Obstetrical Clinic of Charles University, Prague, told the Fourth European Congress of Perinatal Medicine here.

It also enhances the likelihood of premature births and ectopic pregnancies, he said. Further, "abortion frequently reduces woman's future reproductive capability and affects her emotional and sexual life."

He warned that in a review of the literature, "a great sum of serious morbidity following legal artificial termination of pregnancy has been noticed and described in many papers." Most clinics, he said, lose sight of their patients soon after the operation, but long-term studies including subsequent pregnancies are necessary for a true picture of post-abortion complications.

### 2 Million Abortions in 17 Years

Czechoslovak experience is based on some 2,000,000 legal first trimester abortions (voluntary induced abortions are not permitted after the twelfth week), carried out over a period of 17 years. During the first ten years there were 20 maternal deaths connected with the procedure, Dr. Kotásek said, (two per 100,000); since then the rate has decreased.

However, he said, a detailed Prague study concludes that only 57 per cent of pregnancies following induced abortion were carried to term. The spontaneous abortion rate was 2.2 times the "normal" incidence. While reports of cervical incompetence was a rare cause of second trimester miscarriages before legalization of abortion in Czechoslovakia in 1958, ten years later it was reported two to five times more frequently in women who had had interruptions than those who had not. "A very high standard of antenatal care from the end of the first trimester for all women who have had a previous artificial termination of pregnancy is advisable," he said.

### Czechs Smoking More

Medical Tribune World Service

PRAGUE — Despite a policy of no tobacco advertising, despite antismoking clinics, and despite the publicity given to the harmful effects of the weed, cigarette smoking continues to increase in Czechoslovakia. Cigarette sales have tripled since 1946 and now amount to 27 billion annually, or 1900 per capita.

Much of the increase is accounted for by women and children. According to an investigation recently published by the Institute of Health Education in Prague, boys now try their first cigarette before they are ten, girls between the ages of twelve and 13. By the time they are fifteen, every second youngster has at least tried smoking, and every fourth smokes occasionally.

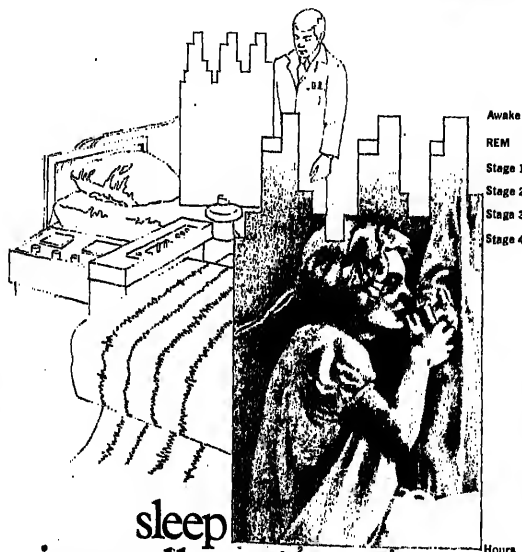
Officials attribute 30,000-40,000 deaths a year, about a fifth of all deaths, to smoking-connected causes.

abortion, since women who do not wish children do not attend fertility clinics, Czechoslovak authors report a sterility rate of 1.3-7 per cent following induced abortion, compared with 2-5 per cent reported elsewhere.

### Sex Attitudes Changed in 30%

Functional sexual disorders are also a common late consequence. Of 200 women who were examined psychologically by one Czechoslovak author, in connection with interruption of pregnancy, more than 30 per cent admitted lower or negative attitudes towards sexuality.

Significant increases in the duration of the third stage of labor and in retained and adherent placenta have also been reported in women who had previously had induced abortions, Dr. Kotásek said.



sleep  
is usually maintained with  
fewer nighttime awakenings...  
a consistent benefit of

**Dalmane**  
(flurazepam HCl) proved by a  
17-night clinical study in the sleep research  
laboratory evaluating effectiveness in  
insomniac patients

Eight patients received no medication on nights 1-4; Dalmane (flurazepam HCl) or placebo on nights 5-9; crossover capsule, nights 10-14; and no medication, nights 15-17. While placebo had no significant effect on sleep maintenance, Dalmane reduced nighttime awakenings by 33.1% when given on nights 5-9, 43.7% on nights 10-14. When four control subjects received placebo on the 10 "drug" nights, awakenings increased 11.5% over baseline.

## IFRP Intrauterine Membrane Disappointing

Medical Tribune World Service

BUENOS AIRES — Discouraging results with a new intrauterine device developed by the International Fertility Research Program (IFRP) were reported here.

Bleeding was the primary problem with the plated-membrane IUD, or intrauterine membrane (IUM), Dr. Michael N. Thomas told the Eighth World Congress on Fertility and Sterility.

Fourteen of the 119 women tested had the IUM removed because of bleeding, said Dr. Thomas, research assistant with the IFRP of the Carolina Population Center, University of North Carolina.

After three months, the net cumulative rate of bleeding/pain removals was

5.9 per 100 women, the pregnancy rate was 1.1, and the expulsion rate was 2.0.

The plated-membrane IUD is a polyethylene device containing 15 per cent barium sulfate. It is approximately 1.5 inches long and 0.005 inch thick. The plates were designed to increase the device's ability to react to uterine contractions. The IUD is strengthened by a "wishbone" reinforcement molded on the bottom.

About half of the study group were less than 25 years old and about 80 per cent had one or two children. After the early setbacks, the IFRP investigators modified the inserter and have been using a similar IUD made of Alathon 20.

"The ongoing studies are designed

not only to develop an improved IUM," said Dr. Thomas, "but also to develop hypotheses concerning the mechanism of action which leads to increased or decreased bleeding in all IUDs."

Coauthors were Drs. Leonard Lurie, of the Western Pennsylvania Hospital, Pittsburgh, and Robert Wheeler, of the Battelle Memorial Institute, Richland, Wash.

### Latex-Leaf IUD

Israeli doctors, on the basis of initial results, pronounced the Anderson-Ansell latex-leaf IUD superior to the Lippes loop and Dalton shield in some respects—notably in low pregnancy rates. Dr. E. Sadovany, of the Hadassah University Hospital, Jerusalem, re-

ported on 187 women from 18 to 40 years in whom the latex leaf was inserted between January, 1973, and March, 1974, and who used it for a total of 1,712 woman-months.

The latex leaf IUD is made of inert silicone rubber impregnated with copper and zinc and is radiopaque, Dr. Sadovany said. The electromechanical interaction of the metallic ions it releases is believed to cause its contraceptive effect.

Its softness was expected to prevent decubitus and irritation of the uterus, with consequent low removal rates due to bleeding and pain. But this did not prove to be the case.

### High Removal Rate

The removal rate was 37.1 per 100 woman-years, compared with 28.9 for the Lippes loop and 14.1 for the Dalton shield, Dr. Sadovany reported. Removal was mainly due to bleeding—23.1 with the latex leaf, against 12.8 with the loop and 6.4 with the shield.

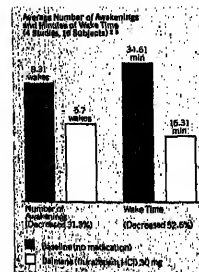
The pregnancy rate, however, was only 1.4, against 12.3 and 4.2 respectively with the two other devices.

The expulsion rate was 4.2 against 12.3 and 1.43.

The investigators commented that the low pregnancy rate, the ease of insertion, and the fact that in some patients with high parity and with slightly enlarged uterus there is relatively little side-effect bleeding, make it worthwhile to try the latex-leaf IUD in larger groups of women.

Coauthors were Drs. W. Z. Polshuk, S. O. Anteby, S. Yarkoni, and Y. Aboulafia.

## confirmed by clinical studies in four geographically separated sleep research laboratories



Using a 14-night protocol, involving eight insomniacs and eight normal subjects, four studies confirmed the sleep-maintaining effectiveness of Dalmane (flurazepam HCl) and the reproducibility of this response. On average, one 30-mg capsule reduced number of awakenings by 31.3% and wake time by 32.6%. In all these studies, Dalmane induced sleep rapidly, an average within 17 minutes; reduced nighttime awakenings; and provided, on average, 7 to 8 hours of sleep without repeating dosage.

## Dalmane (flurazepam HCl) induces and maintains sleep, with relative safety

Dalmane is generally well tolerated; morning "hang-over" has been relatively infrequent. While dizziness, drowsiness, lightheadedness and the like have been noted most often, particularly in the elderly and debilitated, physicians should be aware of the possibility of more serious reactions, as noted in the Complete Product Information.

Before prescribing Dalmane (flurazepam HCl), please consult Complete Product Information, a summary of which follows:

**Indications:** Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; and in acute or chronic medical situations requiring restful sleep. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended.

**Contraindications:** Known hypersensitivity to flurazepam HCl. **Warnings:** Caution patients about possible combined effects with alcohol and other CNS depressants. Caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Use in women who are or may become pregnant only when potential benefits have been weighed against possible hazards. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, use caution in administering to

addiction-prone individuals or those who might increase dosage. **Precautions:** In elderly and debilitated, initial dosage should be limited to 15 mg to preclude over-sedation, dizziness and/or ataxia. If combined with other drugs having hypotensive or CNS-depressant effects, consider potential additive effects. Employ usual precautions in patients who are severely depressed, or with latent depression or suicidal tendencies. Periodic blood counts and liver and kidney function tests are advised during repeated therapy. Observe usual precautions in presence of impaired renal or hepatic function. **Adverse Reactions:** Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported were headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, tachycardia, apprehension, irritability, weakness, palpitations, chest pain, body and joint pains and GI complaints. There have also been rare occurrences of sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, hallucinations, and elevated SGOT, SGPT, total and direct bilirubin and alkaline phosphatase. Periodic rectal exams, e.g., excitement, stimulation and hyperactivity, have also been reported.

**Usage:** Individualize for maximum beneficial effect. Adults: 30 mg usual dosage; 15 mg may suffice in some patients. Elderly or debilitated patients: 15 mg initially until response is determined. Supplied: Capsules containing 15 mg or 30 mg flurazepam HCl.

**REFERENCES:** 1. Kales, J., et al. *Clin. Pharmacol. Ther.* 12:691-697, Jul-Aug, 1971. 2. Karacan, I., Williams, R.L., Smith, J.R. The sleep laboratory in the investigation of sleep and sleep disorders. *Scholarly exhibit at the 124th annual meeting of the American Psychiatric Association, Washington, D.C., May 3-7, 1971.* 3. Pross, J.D. Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley, NJ. 4. Vogel, O.W. Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley, NJ. 5. Denney, W.C. Data on file, Medical Department, Hoffmann-La Roche Inc., Nutley, NJ.

when restful sleep  
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**Dalmane**  
(flurazepam HCl)

One 30-mg capsule h.s. — usual adult dosage  
(15 mg may suffice in some patients).  
One 15-mg capsule h.s. — initial dosage for  
elderly or debilitated patients.

- induces sleep within 17 minutes, on average
- reduces nighttime awakenings
- sustains sleep 7 to 8 hours, on average, without repeating dosage



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## No Ideal Topical Drug Seen for Tinea Pedis

Medical Tribune Report

CHICAGO — Patients who present with symptoms of athlete's foot are best treated by basic hygienic measures and steps to keep the feet cooler, such as loose shoes, sandals, or leaving the shoes off frequently, according to Dr. Leon Goldman, Professor and Chairman of the Department of Dermatology, University of Cincinnati.

"In spite of extensive advertisements in the lay press and television, there is still no ideal type of topical medication for athlete's foot," he told the American Academy of Dermatology.

Renewed attention is being given to topical griseofulvin. With suitable vehicles, the medication may have some value, but further control studies are needed, Dr. Goldman said. Newer synthetic agents available to the practitioner include haloprogen, miconazole nitrate and silver sulfadiazine.

Topical medications should be continued for some time after symptoms improve, unless they are irritating or sensitizing, Dr. Goldman recommended.

Preventive measures should include "simple drying of the skin without using the towel as a saw to tear the skin between the toes," he added. Bland powders are helpful.

He pointed out that the combination of poor hygiene through heavy, sweaty socks, especially nylon and wool, and heavy shoes provides favorable moist conditions for the continued growth of the fungus infection.

## Mexicans Describe Fatal Muscle Hypertonia

Medical Tribune World Service

**MEXICO CITY**—An unusual neurologic disorder, previously undescribed, consisting of severe generalized muscle hypertonia during wakefulness and normal tonia during sleep, has been reported by Mexican investigators.

Drs. Jose Maria Cantu, of the genetics section, biology of reproduction division, and Alfredo Cuellar, head of the department of nutrition, Hospital de Pediatría, Centro Médico Nacional, Mexican Social Security Institute, described one case in which the condition manifested itself at birth and remained unchanged until the infant's death two and one-half months later from bronchopneumonia.

The body stiffness was such that the patient could be moved from dorsal

decubitus to an erect position by supporting him only by his feet and at the nape of the neck. The arms were in flexion, the hands strongly clenched, and the feet in hyperflexion. He remained in that state all the time he was awake; after falling asleep, he gradually relaxed.

### 6 Sibs Affected

Dr. Cantu concluded from the family study that homozygosity of a mutant recessive gene located in an autosome was responsible for the disease. Six sibs of both sexes were indirectly ascertained to have died of the disorder between two and four months of age. The parents were second cousins and had 19 other children.

Attempts to correct the hypertonia with intravenous administration of calcium gluconate two days after birth had no effect, nor did methocarbamol intramuscularly in two months of age, but a week later, a single dose of benzodiazepine produced a mild remission. The neuromuscular impairment had resulted in fetal hypoxia. After the birth of the second affected child, Dr. Cantu said, the mother was able to predict which of the subsequent children would be likewise affected on the basis of the weak fetal movements she felt.

Also present in the infant studied were pharyngoesophageal dyskinesia and cardiopulmonary distress, complicated by bronchopneumonia unresponsive to treatment.

"It is very difficult to know the basic neurologic problem that causes the disease," Dr. Cantu commented. "The EEG findings during the wakeful state can be considered to be within normality for the infant's age, while the abnormal tracing obtained during sleep could be due to brain hypoxia resulting from the respiratory deficiency."

"However, it might be speculated that the underlying cause of the disease is at the brain-stem level, since this structure has been shown to perform the main neural activity in the neonatal period and also to control the sleep-waking cycle."

The discoverers of "thunatophic congenital stiffness" suggest that genetic counseling be instituted on the basis of autosomal recessive inheritance.

Wednesday, February 5, 1973

MEDICAL TRIBUNE

13

## One Man...and Medicine

ARTHUR M. SACKLER, M.D.  
International Publisher, Medical Tribune



### Wanted: Reasons Why

Brinkmanship was no monopoly of John Foster Dulles. Hundreds of millions throughout the world teeter on the brink of starvation; yet social leaders focus on dangers of the year 2,000 instead of getting food to those starving now. Why? Scores of millions hover on the brink of health and die from the ravages of preventable and treatable diseases—yet confidence in doctors and their drugs are constantly undermined. Why? Huge gaps exist in our knowledge—gaps that must be closed through new knowledge if, surviving the threat of war and hunger, we are to progress to new levels of health; yet major sectors of biomedical research are under attack now. Why?

One reads with horrified fascination of the well-intentioned but potentially disastrous efforts of those who would deprive prisoners of their social right to volunteer as subjects for research. Why? Why don't those opposing research on mental patients explain how in heaven's name we are going to help these people with better therapies than those which are presently available?

Why are "rights of the individual" used as the basis by both civil libertarians and the "Right-To-Life" groups to challenge valid and fundamental scientific investigation? Why do not those who believe in the "Right-To-Life" of the fetus join forces with those who have pointed out the devastating effects of dietary inadequacy on scores of thousands of our unborn and newly born? Why don't those who oppose research in pediatrics explain to us how in heaven's name we will continue the advances in pediatric medicine without research with children?

### Threat to Biomedical Science

The threats to the biomedical sciences are like those of a multi-headed hydra—no sooner is one chopped off than one or two more appear. The Department of Agriculture has restricted the import of animals, including higher primates, with senseless disregard of the implications for therapeutic and basic research. Why? Government regulatory actions constantly proliferate more and more restrictions without regard to compensation. Why? Simplistic slogans and simplistic solutions are proposed without basis in experience or study but apparently primarily on "the courage of their confusions."

Why the continuing escalation of attacks on medicine and men of medicine? Why the ever-increasing threats to research in the biomedical sciences? Why have we progressed so little in shortening the interval between discovery and application in this, the day of instantaneous communication and mass education? Why do we revert again and again to the earlier periods of anti-science when anatomy depended upon stolen bodies and when the efforts of scientists were challenged by the dogmas of established beliefs?

The which hunters of an earlier day burned the bodies of their victims

whom they could not understand or accept. Are we entering now into the new era of witch hunting directed at science and scientists in which the reputations of researchers will be "burned at the stake?"

Why? Is the critical question. Can it be that logic, unhappily, still takes second place to emotion; that the interest of the many still takes second place to the vested interests of a few individuals?

What are the ulterior motives? Are they protection of personal credos and dogmas and the imposition of these on others? Are they the need to create issues by those seeking political and social change? Do they reflect new forms of personal gain—rewards in the coinage of publicity and press prominence?

### Misleading Distortion

One can accept the right of individuals to defend their own beliefs but not necessarily to impose them on others. One can defend the right of individuals who seek social change. But one cannot accept the misleading distortion of issues for disguised political or personal motives, for publicity or prestige.

It is tragic that the opportunity to do biomedical research is being undermined, the freedom with which to disseminate its findings restricted, and the time necessary for its application in the biomedical area being constantly lengthened. The crusaders of our day, whether for religious or consumer advocacy, have learned the power of publicity pressure in the political arena and on the bureaucracies of government. They have learned to use sensationalism to get visibility in the public press and on the TV screen. Scientists are only now being shaken in their environments, apparently still much too cloistered. The scientific conscience was aroused by the atomic bomb. It is time that scientific consciousness recognize what is happening with these new, developing abuses of both the scientific method and of scientists.

### ECTOPIC BEAT

The great tragedy of Science—the slaying of a beautiful hypothesis by an ugly fact.

Thomas Henry Huxley (1825-95)  
Collected Essays, "Biogenesis and Abiogenesis"

## GE Technique Spots Subtle Heart Defects



Heart defects undetected by routine electrocardiograms may now be identified by a technique being developed by G.E. The technique combines a mini-computer with a superadditive electronic "heart" that provides a much broader and more accurate range of heart sounds, which are computer-analyzed on the spot for interpretation and diagnosis.

## For UN Staffers in Geneva, Blues Often Mar Blue Skies

Medical Tribune World Service

**GENEVA**—In the eyes of many Swiss, members of the International staff of the United Nations Organization lead an enviable existence, with high salaries, no income tax, and certain diplomatic privileges, including cheap liquor and gasoline and virtual immunity to parking tickets.

But, in fact, emotional problems are common among these international careerists. The single woman, for instance, may have to cope with loneliness in a huge faceless organization, along with the difficulties of adapting to an alien culture.

When the menopause approaches, women in this situation may suffer from depression to an unusual degree. *MEDICAL TRIBUNE* was told in an interview here by Dr. Jean-Felix Dulac, head of the U.N. medical service. He cited cases of alcoholism, and attempted suicide.

### Stresses May Be Severe

Dr. Dulac pointed out that the stresses incident to taking a job with a U.N. organization may be severe, and even top executives may need as much as two years before settling down to effective work.

The stresses are not confined to the U.N. organizations in Switzerland, Dr. Dulac noted that they are also common in staff in New York and Paris. One difficulty in treatment of such a patient is language. In Geneva, for example, many psychiatrists and other psychotherapists are fluent in English (and often German and Italian) as

well as their native French, but may not pick up important nuances during interviews with English-speaking patients.

"We try to avoid taking any step which might lead the patient to become overconscious of her problems," Dr. Dulac said. "This is not so much a difficulty with an American patient, from whom contact with a psychiatrist is not considered unusual. For a European patient, on the other hand, 'psychiatrist' can be misinterpreted."

The U.N. medical service has learned from experience to watch for signs of possible emotional instability among staff and also among job applicants. Absenteeism is one of the first signals of approaching trouble.

Applicants for U.N. jobs are now screened for their ability to adapt to a new cultural situation.

### High BP Found in 42%

Medical Tribune Report

**NEW YORK**—A recent survey of 1,545 persons by the lobby of the Empire State Building has shown that "42 per cent of the New York population is walking around with high blood pressure," the Preventive Medicine Institute—Strang Clinic has reported.

Almost half (45 per cent) of men between the ages of 40 and 64 had blood-pressure readings above normal, and nearly 40 per cent of women in the same age-group had readings that "would require medical attention," the survey showed. In the under-40 group, women fared much better than men.

Merrell

## Tenuate® (diethylpropion hydrochloride N.F.)

### BRIEF SUMMARY

**INDICATIONS:** Tenuate is indicated in the management of exogenous obesity as an adjunct to diet and exercise. The limited effectiveness of Tenuate in the treatment of exogenous obesity is due to the fact that the drug does not act on the central nervous system.

**CONTRAINDICATIONS:** Advanced arteriosclerosis, hypertension, coronary artery disease, glaucoma, agitated states.

**Warnings:** Tenuate may cause drowsiness, dizziness, or vertigo. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**Usage:** Tenuate should be taken as directed. It should not be used for more than 12 weeks. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**Side Effects:** Tenuate may cause drowsiness, dizziness, or vertigo. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**Precautions:** Tenuate should be taken as directed. It should not be used for more than 12 weeks. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**How to Use:** Tenuate should be taken as directed. It should not be used for more than 12 weeks. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**Warnings:** Tenuate may cause drowsiness, dizziness, or vertigo. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

**Contraindications:** Tenuate is contraindicated in patients with advanced arteriosclerosis, hypertension, coronary artery disease, glaucoma, agitated states, and a history of alcoholism or drug abuse.

**Side Effects:** Tenuate may cause drowsiness, dizziness, or vertigo. It should not be used in patients with a history of alcoholism or drug abuse. It should not be used in patients with a history of epilepsy or other seizure disorders.

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MERRELL-NATIONAL LABORATORIES  
Division of Richardson-Merrell Inc.  
Kenilworth, Ohio 44139

# Nothing motivates like early weight loss

# Help motivate with Tenuate® (diethylpropion hydrochloride N.F.)

# Merrell



# The Pseudo-ulcer



## Ulcer-like symptoms: no G.I. pathology

The patient is convinced it's an ulcer. However, symptoms are not quite typical, and x-ray findings are negative. These findings and the results of nutritional diagnostic procedures exclude an organic basis for the patient's complaints. A diagnosis of "upper functional gastrointestinal disorder" is made, which is supported by the fact that episodes of painful symptoms coincide with episodes of excessive anxiety, as indicated by the history.

It may be useful to explain to the patient the mechanism by which emotions upset normal G.I. functioning, resulting in hypersecretion and hypermotility and thus causing such symptoms as nausea and epigastric pain. In upper functional gastrointestinal disorders, counseling by the primary physician can often help the patient to understand how excessive anxiety may cause flare-ups of G.I. symptoms.

A disproportionate number of patients seen by the general practitioner suffer from functional disorders, as do more than half of those seen by the gastroenterologist. Where milder cases may respond to counsel-

ing alone, if symptoms are severe and disabling to any degree, a suitable regimen may include medication to produce the symptoms and the excessive anxiety that often provokes these distressing symptoms. In these cases, Librax as an adjunct is a very useful tool in the course of therapy. Its dual action can often relieve both painful symptoms and excessive anxiety, because each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cildinium Br. The anxiolytic action of Librax® (chloridazepoxide HCl) makes Librax exceptional among drugs for certain gastrointestinal disorders associated with excessive anxiety: the cildinium bromide (Quarzan®) component furnishes dependable antiserotory-antispasmodic action. Dosage is flexible; it may be adjusted according to your patient's requirements within the range of 1 or 2 capsules three or four times daily, up to 8 capsules daily in divided doses.

An adjunct in anxiety-related upper functional G.I. disorders

**Librax®**

Each capsule contains 5 mg chloridazepoxide HCl and 2.5 mg cildinium Br.

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Symptomatic relief of hypersecretion, hypermotility and anxiety and tension states associated with organic or functional gastrointestinal disorders; and as adjunctive therapy in the management of peptic ulcer, gastritis, duodenitis, irritable bowel syndrome, spastic colitis, and mild ulcerative colitis.

**Contraindications:** Patients with glaucoma; prostatic hypertrophy and benign bladder neck obstruction; known hypersensitivity to chloridazepoxide hydrochloride and/or cildinium bromide.

**Warnings:** Caution patients about possible combined effects with alcohol and other CNS depressants. As with all CNS-acting drugs, caution patients against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Though physical and psychological dependence have rarely been reported on recommended doses, use caution in administering Librax (chloridazepoxide hydrochloride) to known addiction-prone individuals or those who might increase dosage without medical supervision (including convulsions), following discontinuation of the drug and similar to those seen with barbiturates, have been reported. Use of any drug in

pregnancy, lactation, or in women of childbearing age requires that its potential benefits be weighed against its possible hazards. As with all anxiolytic drugs, an inhibiting effect on lactation may occur.

**Precautions:** In elderly and debilitated, limit dosage to smallest effective amount to preclude development of ataxia, dizziness or confusion (not more than two capsules per day initially; increase gradually as needed and tolerated), with other psychotropic agents (e.g., sedatives, tranquilizers, and other psychotropics) seems indicated, carefully consider timing of doses. In patients with impaired renal or hepatic function, extra precautions are indicated, particularly in use of potent sedatives. Observe usual precautions in presence of impaired renal or hepatic function. Paradoxical reactions (e.g., excitement, stimulation and acute rage) have been reported in psychiatric patients with evidence of impending depression; suicidal tendencies may be present and protective measures necessary. Variable effects on blood coagulation have been reported very rarely in patients receiving the drug and oral anticoagulant; causal relationship has not been established clinically.

**Adverse Reactions:** No side effect or manifestation not seen with either compound alone have been reported with Librax. When chloridazepoxide hydrochloride is used alone, drowsiness, ataxia and confusion may occur, especially in the elderly and debilitated. These are reversible in most instances by proper dosage adjustment. Side effects are also occasionally observed at the lower dosage ranges. In a few instances, symptoms have been reported. Also encountered are isolated instances of ataxia, dizziness, edema, minor menstrual irregularities, nausea and constipation, extrapyramidal symptoms, increased and decreased blood-alcohol levels, changes in EEG patterns (low-voltage fast activity) may appear during and after treatment; blood dyscrasias (including agranulocytosis), jaundice and hepatic dysfunction have been reported occasionally with chloridazepoxide hydrochloride, making periodic blood counts and liver function tests advisable during protracted therapy. Adverse effects reported with Librax are typical of sedatives and anxiolytics, and include drowsiness, blurring of vision, urinary incontinence and constipation. Constipation is more common when Librax therapy is combined with other antispasmodics and/or low residue diets.



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Nutley, New Jersey 07110

The Only Independent Weekly Medical Newspaper in the U.S.

## Medical Tribune

and Medical News  
Published by Medical Tribune, Inc.

### Some News Items . . .

**ITEM #1**—Blue Cross-Blue Shield of Greater New York is asking for a 27.8 per cent average rate increase for hospital charges to go into effect March 1, 1975. The last increase totalled 7.4 per cent on April 1, 1973. Of the present increase, 22.2 per cent will be for costs of current benefits and 5.6 per cent for proposed new benefits.

**Item #2**—The increases are attributed to "rising prices for food, fuel and other

supplies, and higher collectively bargained hospital wages, salaries and fringe benefits."

**Item #3**—New York City's Health and Hospitals Corporation is seeking to raise its present per diem from Blue Cross of \$117 a day for in-patient hospitalization to as much as \$200 a day, reportedly comparable to reimbursement rates in private and voluntary institutions.

### . . . Relevant Queries . . .

**DO** PRESENTLY proposed government health insurance plans project this rate of inflation and per diem hospitalization at almost \$200? How will the government meet "rising prices for food, fuel and other supplies, and higher collectively bargained hospital wages, salaries and fringe benefits"? Cutting costs of drugs and doctors' fees will not suffice. As inflation escalates cost, will services be cut and availability and duration of hospitalization restricted for beneficiaries of federal programs? Are government projections for

administrative costs comparable to those of the Blue Cross and Blue Shield plans? What are these projections and when were they made?

How long will it take our governmental agencies to realize that no national health insurance program will be viable without massive expansion of health manpower and preventive medicine; without more effective action in respect to adding cigarettes and alcohol, and without the development of new medicines to reduce both the need for and the duration of hospitalization?

### . . . And Some Major Questions

**G**OOD preventive medicine, more medical and earlier diagnosis of treatable disorders are realistic national needs; not rhetorical posturing and phony bureaucratic "cost effectiveness" proposals. America has seen the type of bureaucratic regulation which has virtually destroyed the American railroad system and has crippled our postal service; such bureaucratization can

also bankrupt or cripple our presently functioning albeit not perfect, health care distribution system.

Why don't our "double-blind" health officials who require well-controlled experiments for individual drugs and devices test their proposals? Why are there no prototype pilot projects to check the validity of their proposed changes in our health care system? **A.M.S.**

### Where Are All The Unmarried Men?

**T**HE ABOVE question is taken from an article in a recent issue of the *Statistical Bulletin*, and refers solely to Americans. On the basis of the 1970 census of the population, the number of unmarried men aged 18-29 per 100 unmarried women aged 16-24 is 110 in the Pacific states; it is 104 in the South Atlantic states; in the remaining seven geographic subdivisions of the U.S., unmarried men are outnumbered by unmarried women with the greatest discrepancy occurring in the East North Central states where there are 88 such men for every 100 such women.

We cite some outstanding figures for

unmarried men per 100 unmarried women, such as 213 in Alaska, 146 in Hawaii, 120 in Nevada, 120 in Rhode Island, 115 in Virginia, 112 in South Carolina and 111 in California. Unmarried women exceed unmarried men by more than 15 per cent in Minnesota, Pennsylvania, Ohio, Iowa, West Va. and Utah.

How does one explain these geographical concentrations of single men? Alaska is our last frontier but that certainly is not true of Hawaii, Rhode Island or Virginia.

Perhaps now that the word is 'out the ratios will be readjusted.

### Emergency Medical Service

**CLINICAL QUOTE:** "You can't predict when you go out on an emergency which call will need advanced life support. The older patient who falls and breaks a hip may have done so because of arrhythmia. A heart problem may cause an automobile accident, and then, arrhythmic complications may lead to cardiac arrest en route to the

hospital." (Dr. Costas T. Lambrew, Chairman, Department of Medicine at Nassau County Medical Center, Long Island, N.Y., after analyzing the EKG's of 9,000 patients—1728 with chest pain, 4334 with illnesses other than chest pain, 2744 trauma victims and 194 unclassified patients. See page 1.)



"Please make the check payable to Dr. Jakyl end/or Mr. Hyde."

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### LETTERS TO TRIBUNE

#### His Own Spokesman

In a recent editorial (MT, Dec. 4, 1974) you asserted that the A.M.A. has long been the "official spokesman" of medicine, advocating the views of the majority of its members. That is much like saying a labor union or a government represents the views of the minority. This is not true. In fact, it is fraud to perpetuate the myth of any person or group "representing" a given individual. Only I can represent my views. I might give another person the authority to represent my views on a certain matter, but there is no way he can "represent" me in a broad sense. Therein lies the futility and fallacy of democracy, voting, government or coercion in any form.

It is time we recognize the individual. He is the possessor of inalienable rights to his life, liberty and property. He and he alone is sovereign. This is one of the most potent facts of life. If only enough men will act according to their nature qua man and abhor the tribe and all forms of collectivism, altruism and sacrifice, it could be a better world.

All *any man* has to do to eliminate evil is to say NO! This includes physicians. No government or man-made law that denies any man his inalienable rights is moral. We must say NO to all forms of coercion. Only then will we be free. Free to live our lives in peace and prosperity. Only then will man be able to reach his full potential. Yours for reason & liberty,

ROBERT S. BORDEN, M.D.  
Gryton, Mass.

#### Genetic Counseling

I read with interest Dr. Kurt Hirschhorn's "In Consultation" article, "What is New and Important in Genetic Counseling?" (MT, Dec. 18, 1973).

In regard to where to turn for genetic counseling help, I would like to call your attention to the National Genetics Foundation, (250 West 57th Street, New York, N.Y. 10019, (212-265-3166) which offers a unique service to the physician by providing assistance with any genetic or genetically related problem. The National Genetics Foundation operates a network of genetic centers involving 47 medical teaching institutions throughout the United States and Canada. Many of its participating centers have the trained

personnel and sophisticated laboratory facilities to perform tests the private physician requires for diagnostic confirmation. The headquarters of the National Genetics Foundation acts as a clearinghouse by directing physicians and/or the lay public to the appropriate medical center with the most comprehensive facilities for the particular problem involved.

In the past four years physicians associated with hospitals throughout the country have been utilizing this important service which is often vital to those physicians involved in the practice of pediatrics, obstetrics, or family medicine. Services are secured by contacting the National Genetics Foundation directly at the above address, or by telephone.

GEORGE W. MELCHER, JR., M.D.  
New York, N.Y.

#### Reviewing by What Peers

I could not agree more with the letter by Dr. James K. Thelsen (MT, Dec. 18, 1974) concerning the fact that PSRO has not been accepted—nor should it be. Congress itself has two bills pending concerning the repeal of this law and each of us should write our congressmen requesting action on these bills—HR 12256 (Mr. Rarick, Mr. Parris, Mr. Lott, Mr. Flynn—Jan. 23, 1974) and HR 15266 (Mr. Broyhill—June 6, 1974). Nothing can be changed if we don't move to change it ourselves.

H. TAYLOR YATES, JR., M.D.  
Alexandria, Va.

#### Dr. Coolidge's Tube

\* I was pleased to see you publish a picture, and to know that Dr. William D. Coolidge is still alive. As you well know, the invention by Dr. Coolidge of the hot cathode Roentgen tube with an electrically heated cathode permitted close and careful regulation of the quality and quantity of X rays emitted by the tube. Prior to his invention, the old gas tube was very unreliable and unpredictable, and could not be carefully calibrated.

This remarkable man made Roentgen's invention practical.

Many thanks for your fine publication.

D. F. CASPARATTI, M.D.  
Fallon, Nev.





# FDA Release of Dalkon Shield Stirs Controversy

Continued from page 1

"In other tests, we took shields that were actually removed from women wearers and compared them with monofilament models also removed from patients," Dr. Tatum said. "The outer surfaces of all IUD tails were carefully sterilized. These specimens, by the way, came from many different clinics throughout the country. Still, the results showed that, while none of the monofilament grew any bugs, the inside of the Dalkon tails were teeming with them. Forty per cent of all Dalkon tails were positive for aerobic bacteria and 80 per cent were positive for anaerobic bacteria. Most of them of course contained several different species."

At the A. H. Robins Company in Richmond, Virginia, the problem is stated a bit differently. "We're changing the string to stop a controversy, but we don't think it means a thing," Dr. Jack Friend, Vice-President for Research and Development told Medical Tribune. Robins research also counters Dr. Tatum's findings with tests on the Dalkon tail dipped in human saliva, rather than water or saline. In these tests, the more viscous solution took 48 hours to climb 5 mm. up the tail. Dr. Freund and others at Robins say there is thus no real evidence that bacteria could ascend by capillary action in the viscous medium of the body's fluids.

The multifilament tail—with the filaments artificially separated here to show detail—is the focus of criticism of the Dalkon Shield IUD.

Giving this as the basis for the company's refusal to recall the device, or even to admit that there may be increased risk with the Dalkon, Dr. Freund concluded, "We don't have to apologize to anybody for the way we've acted."

"Robins has been recalcitrant from the beginning," Dr. Richard P. Dickey of Louisiana State University Medical Center told Medical Tribune. He and Dr. Emanuel Freedman were the two F.D.A. committee members who resigned in protest of the resumed sales.

"By insisting that nothing is wrong with the multifilament tail, the manufacturer is confusing many doc-

tors. I've even heard of physicians who inserted the device during the moratorium. Now that it has been lifted and there is no recall program, there's a great temptation for someone with a large supply of multifilament Dalkons to save his investment and continue to insert them."

## Bacteria on Tail Surfaces

Dr. Freund and others at Robins have argued that there is no more danger from bacterial contamination with the multifilament Dalkon than with monofilament IUDs. His research has also called attention to the presence of bacteria on the surface of all IUD tails. "Ninety per cent of bacterial accumulation on the Dalkon Shield tail

occurred on its surface," his report to the F.D.A. stated, a structural feature common to all IUDs.

"The problem of bacterial contamination associated with IUDs is far from new," Dr. Tatum concurred. "Specific research on endometrial infection due to IUD insertions began in 1966 with Dr. Daniel Mitchell's work. Mitchell showed that you always introduce bacteria into the sterile field of the uterus when you insert an IUD through the cervix, which is usually positive for a number of organisms."

"He also found by transfundal culture that, while bacteria do reside on part of the IUD tail outside the cervix, the cervical mucus apparently prevents these from ascending along the

surface of the tail into the endometrium after the initial contamination at the time of insertion is overcome (usually, within two to 10 days).

## Jelly Blocks Bacteria

However, in experiments in which the tails of all IUDs were placed in bacterial solutions beneath a layer of sterile petroleum jelly (simulating the bacterial barrier of the cervical mucus), Dr. Tatum and Mr. Fiedler-Schmidt found that only the Dalkon tail was contaminated with bacteria above the level of the jelly. In other words, he explained, the bacteria could travel along the surface of the monofilament, but only as far as the petroleum jelly, while in the case of the

# after taking a potent analgesic 360 times in 9 days



Dalkon tail, they were protected from the jelly by the sheath around the filaments as they made their way upwards, past the knot in the lower end of the tail and up to the base of the shield itself.

Dr. Tatum has not shown that the bacteria pass through the double knot at the base of the Shield itself, but he pointed out that his laboratory tests for this possibility were conducted over a period of days, rather than the months or years that the IUD would be worn by a patient. However, he has found Dalkon tails with inner sheaths. More significantly, he noted, as a woman's uterus expands during pregnancy, the IUD tail is often drawn up past the cervix. In the case of the Dalkon tail, bacteria inside the sheath, protected en route from bactericidal action by the cervix, could then emerge to attack

the fetus. This possibility would coincide with the major reported hazard of the Dalkon Shield, he said: second trimester spontaneous abortion, especially dangerous because of the large size of the fetus.

## 'Restricted' Sales Allowed

Robins itself first reported pregnancy-related complications with the shield in June of last year, and agreed to ban sales of the device until after F.D.A. investigations. After hearing from both sides for several months, the F.D.A. first requested that the sales moratorium be continued, then, more recently, assumed of its own accord and allowed resumption of "restricted" sales (i.e., a computerized registry system at Robins will now keep track of all new insertions).

"It is not apparent from the available

information that the safety and efficacy of the Dalkon Shield is significantly different from the other IUDs," the F.D.A. statement said.

While there have been 219 reported septic abortions in women wearing the Dalkon (compared to 68 in all other IUDs combined), as well as 14 deaths from Dalkon-associated sepsis (compared to eight from all other IUDs combined), an F.D.A. spokesman for Dr. John Jennings, Associate Commissioner for Medical Affairs, said the data is misleading.

"For one thing, data on the Dalkon has been more available to us, generally. In addition, it became very popular in a compressed period of time, when there was a greater sensitivity to IUD results. Perhaps most significant is the lack of any denominator to put the numbers we have into perspective. We

know about how many shields have been manufactured, but how many were inserted, nor how long they remained in place. Without this, we can't really compile any hard data."

Another F.D.A. spokesman emphasized that the device was "never banned," and that the release of the sales moratorium does not represent a reversal of a former decision, nor the overruling of the Advisory Committee's recommendation to continue the moratorium. "Just because the Advisory Committee makes recommendations," he said, "the Commissioner doesn't have to act on every one of them."

## Countries' Wishes Observed

At the international level, a Robins spokesman explained, "We went along with whatever health authorities in each country said. If they wanted to stop using them, we stopped shipments. If not, sales continued." He added that, despite the controversy, sales of the Dalkon Shield have never been suspended in France, Australia, or South Africa. More than 600,000 Dalkons were shipped to several foreign countries by the Agency for International Development (AID), prior to the F.D.A. investigations.

Nevertheless, Dr. R. T. Ravenholt, Director of Population at AID, still has 160,000 left over. This is because the moratorium on use of the Dalkon is still in force at AID, he said, adding that chances are small that the agency, which is the main source of contraceptives for the world's developing countries, will use the device in the future, even with its new tail.

"The patient registry system mad follow-up now required for inserting a Dalkon are just not feasible for our programs," he said. "We don't have the manpower to monitor results in places like Pakistan, Indonesia, Korea, and Africa. So we'll hold off on the Dalkon until further data accumulates—which means obtaining favorable results with the new version on a large number of women in the United States. That's going to take a long time, so we have no basis for renewing use of the device in the near future."

"We have no organized recall program either, but of course we're working to recover whatever monies we can on the unusable

## PPFA Ban Continues

The verdict on the Dalkon at Planned Parenthood Federation of America (PPFA) is the same: the official ban still holds in its 700 clinics, despite the removal of the F.D.A. moratorium. As to the use of the monofilament model, PPFA said in a statement that it would "reserve judgment of any such new model, pending careful review of a such device . . . by the Federation's National Medical Advisory Committee."

Dr. Elizabeth Connell, Chairperson of the Committee, pointed out that the Dalkon Shield controversy "clearly underscores the need, as stated previously by the Committee, for pleading strong statutory authority with the F.D.A. to regulate medical devices, including IUDs."

PPFA Director of Information and Education, Robin Elliot, added that any new model of the Dalkon would now be considered as a research project by the Federation, and not a device for general use in its clinics.

## how big a dose will now bring relief if it is a narcotic?

"Tolerance is an ever-present hazard to continued use of narcotics. . . . The very first dose diminishes the effects of subsequent doses." And, as increasing amounts of narcotics are required to control pain, distressing adverse effects—(nausea, hypotension, constipation, etc.)—can needlessly debilitate the patient.

1. Badoev, M. S. A look at narcotic and non-narcotic analgesics. Postgrad Med. 49:102, June 1971.

## how big a dose will now bring relief if it is Talwin?

Chances are, the same 50 mg. Talwin Tablet you prescribe originally will continue to provide good pain relief. Talwin can be compared to codeine in analgesic efficacy: one 50 mg. tablet appears equivalent in analgesic effect to 50 mg. (1 gr.) of codeine. However, patients receiving Talwin Tablets for prolonged periods face fewer of the consequences you've come to expect with narcotics. There should be fewer "adverse effects" on her way of life.

Tolerance rears: Tolerance to the analgesic effect of Talwin Tablets is rare.

Dependence rare: During three years of wide clinical use, there have been a few reports of dependence and of withdrawal symptoms with orally administered Talwin. Patients with a history of drug dependence should be under close supervision while receiving Talwin orally.

In prescribing Talwin for chronic use, the physician should take precautions to avoid increases in dose by the patient and to prevent the use of the drug in anticipation of pain rather than for the relief of pain.

Generally well tolerated by most patients: Infrequently causes decrease in blood pressure or tachycardia; rarely causes respiratory depression or urinary retention; seldom causes diarrhea or constipation. Acute, transient CNS effects, described in product information, have occurred in rare instances following the use of Talwin Tablets. If dizziness, lightheadedness, nausea, or vomiting is encountered, these effects may decrease or disappear after the first few doses.

See important product information for adverse reactions, patient selection, prescribing and precautionary recommendations.

in chronic pain of moderate to severe intensity

**Talwin** 50 mg. Tablets  
brand of  
**pentazocine**  
(as hydrochloride)

Talwin Tablets brand of pentazocine (as hydrochloride)

Analgesic for Oral Use—

Indications: For the relief of moderate to severe pain.

Contraindications: Talwin should not be administered to patients who are hypersensitive to it.

Warnings: Drug Dependence. There have been instances of psychological and physical dependence in patients receiving Talwin Tablets for prolonged periods of time. Dependence is more likely to develop in patients with a history of drug abuse and, rarely, in patients without such a history. Abrupt discontinuance following prolonged use may cause withdrawal symptoms. There have been a few reports of dependence and withdrawal symptoms in patients receiving Talwin Tablets who have been administered the drug for prolonged periods of time. Patients with a history of drug abuse should be under close supervision while receiving Talwin Tablets.

Tolerance. Tolerance to the analgesic effect of Talwin Tablets is rare.

Dependence. Dependence to the analgesic effect of Talwin Tablets is rare.

Withdrawal Symptoms. During three years of wide clinical use, there have been a few reports of dependence and of withdrawal symptoms with orally administered Talwin. Patients with a history of drug dependence should be under close supervision while receiving Talwin orally.

In prescribing Talwin for chronic use, the physician should take precautions to avoid increases in dose by the patient and to prevent the use of the drug in anticipation of pain rather than for the relief of pain.

Generally well tolerated by most patients: Infrequently causes decrease in blood pressure or tachycardia; rarely causes respiratory depression or urinary retention; seldom causes diarrhea or constipation. Acute, transient CNS effects, described in product information, have occurred in rare instances following the use of Talwin Tablets. If dizziness, lightheadedness, nausea, or vomiting is encountered, these effects may decrease or disappear after the first few doses.

See important product information for adverse reactions, patient selection, prescribing and precautionary recommendations.

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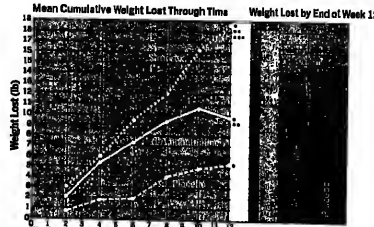
See important product information for adverse reactions, patient selection, prescribing and precautionary recommendations.

# SANOREX® IN OBESITY

(MAZINDOL®) TABLETS, 1 mg and 2 mg.

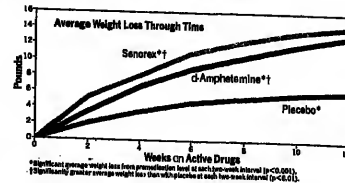
the soft underbelly of American health

## AS EFFECTIVE AS d-AMPHETAMINE



In a double-blind study of 40 obese patients (all of whom completed the study), Sanorex (1 mg t.i.d.) was more effective than either placebo or d-amphetamine (5 mg t.i.d.) in helping patients lose weight.

The 14 patients on Sanorex experienced a substantially greater mean weight loss—1½ to 2 lb/wk, as compared with 1 to 1½ lb/wk for the 14 d-amphetamine patients throughout the 12-week phase of active medication. After the sixth week, the superiority of Sanorex became increasingly evident. And as treatment progressed, so did weight loss in patients on Sanorex—whereas after the tenth week, patients on d-amphetamine began to regain some weight.



In a double-blind study of 90 obese patients (all of whom completed the study), Sanorex (1 mg t.i.d.) was more effective than either placebo or d-amphetamine (5 mg t.i.d.) in helping patients lose weight.

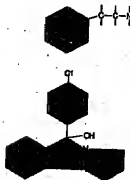
By the end of the third week of active medication, weight loss in the 20 d-amphetamine patients began to plateau, and by the end of the fifth week, these patients began to regain some weight. On the other hand, the 15 patients on Sanorex continued to lose weight throughout the six-week course of therapy.

In a double-blind study of 93 obese patients (all of whom completed the study), 30 patients received Sanorex (1 mg t.i.d.), 31 received placebo, and 32 received d-amphetamine (5 mg t.i.d.). During the 12-week phase of active medication, patients on Sanorex lost an average of 14.1 lb, compared with 13.1 lb for d-amphetamine patients and 5.6 lb for placebo patients. Throughout the active medication phase, 63% of patients on Sanorex lost more than 1 lb/wk, compared with 36% of the d-amphetamine group and 25% of the placebo group.

## BUT WITH CERTAIN DIFFERENCES

Although the pharmacologic activity of Sanorex and that of amphetamines are similar in many ways (including central nervous system stimulation in humans and animals, as well as production

### Different Chemical Structure



An important chemical similarity between amphetamines and all other prescription anorexants except Sanorex is the basic phenethylamine structure to which their differentiating chemical radicals are attached.

An important chemical difference between Sanorex and all other prescription anorexants is that Sanorex is an isodol, it does not contain a phenethylamine structure.

of stereotyped behavior in animals), animal experiments suggest that there are differences. Sanorex also differs in basic chemical structure from amphetamines and all other prescription anorexants.

### Different Neurochemical Action

**Action of d-Amphetamine** In animal studies, d-amphetamine (like intake of food) activates afferent neurons leading to appetite in the hypothalamus. Resulting release of norepinephrine also suppresses norepinephrine synthesis. Thus, increasingly larger doses of d-amphetamine become necessary to produce an effect.

**Action of Sanorex (mazindol)** After intake of food stimulates the release of norepinephrine from the efferent neuron, Sanorex blocks its re-uptake without disturbing normal synthesis and release.

\*The significance of these differences for humans is uncertain.

### Simplicity and Flexibility of Dosage

Simple one-a-day dosage is facilitated by 2-mg tablets (taken 1 hour before lunch).

New flexibility (for the patient in whom 1 mg t.i.d. is preferred) is now facilitated by new 1-mg tablets (taken 1 hour before meals).

For Brief Summary, please see facing page.

## SANOREX® (MAZINDOL®)

**References**  
1. Kornhaber A: Problems and current concepts in the treatment of obesity. Scientific Exhibit presented at the New York State Academy of Family Physicians 28th Annual Scientific Convention, Molokai, HI, May 8-10, 1973.  
2. DeFuria EA, Chertoff LB, Cohen A: Double-blind clinical evaluation of mazindol, dexfenproporexamine, and placebo in treatment of exogenous obesity. *Int J Obes Relat Metab Dis* 1973; 3:355-366.  
3. Varnock BJ: Practical considerations for managing obese patients: initial interview and effective treatment in the office. Scientific Exhibit presented at the American Medical Association, 27th Clinical Convention, Anaheim, Calif, Dec 1-4, 1973.

**Indications:** In exogenous obesity, as a short-term (a few weeks) adjunct in a weight reduction regimen based on caloric restriction. The limited usefulness of agents of this class should be measured against possible risk factors.

**Contraindications:** Glaucoma; hypersensitivity or idiosyncrasy to the drug; agitated states; history of drug abuse; during or within 14 days following administration of monoamine oxidase inhibitors (hypertensive crisis may result).

**Warnings:** Tolerance to many anorectic drugs may develop within a few weeks; if this occurs, do not exceed recommended dose, but discontinue drug. May impair ability to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, and patient should be cautioned accordingly.

**Drug Interactions:** May increase the hypotensive effect of guanethidine; patients should be monitored accordingly. May markedly attenuate the effect of antihypertensive agents (e.g., levorotated or isoproterenol) for shock (e.g., from a myocardial infarction), extreme care should be taken in monitoring blood pressure at frequent intervals and instituting pressor therapy with a low initial dose and careful titration.

**Drug Dependence:** Mazindol shares important pharmacologic properties with amphetamines and related stimulant drugs that have been extensively abused and can produce tolerance and severe psychological dependence. Manifestations of chronic over-dosage or withdrawal with mazindol have not been determined in humans. Abstinence effects have been observed in dogs after abrupt cessation for prolonged periods.

There was some demonstration of the drug in monkeys. EEG studies and "killing" scores in human subjects yielded equivocal results. While the abuse potential of mazindol has not been further defined, possibility of dependence should be kept in mind when evaluating the desirability of including the drug in a weight-reduction program.

**Use in Pregnancy:** In rats and rabbits an increase in neonatal mortality and a possible increased incidence of rib anomalies in rats were observed at relatively high doses. Although these studies have not indicated important adverse effects, the use of mazindol in pregnancy or in women who may become pregnant requires that potential benefit be weighed against possible hazard to mother and infant.

**Use in Children:** Not recommended for use in children under 12 years of age. **Precautions:** Insulin requirements in diabetes mellitus may be altered. Smallest amount of mazindol feasible should be prescribed or dispensed at one time to minimize possibility of overdose. Use cautiously in hypertension, with monitoring of blood pressure, and in patients with severe hypertension or in symptomatic cardiovascular disease including arrhythmias.

**Adverse Reactions:** Most commonly, dry mouth, tachycardia, constipation, nervousness, and insomnia. **Cardiovascular:** Palpitation, tachycardia. **Central Nervous System:** Overstimulation, restlessness, dizziness, insomnia, dysphoria, tremor, headache, depression, drowsiness, weakness. **Gastrointestinal:** Dryness of mouth, unpleasant taste, diarrhea, constipation, nausea, other gastrointestinal disturbances. **Skin:** Rash, excessive sweating, clamminess. **Endocrine:** Impotence, changes in libido have rarely been observed. **Eye:** Long-term treatment with high doses in dogs resulted in some corneal opacities, reversible on cessation of medication; no such effect has been observed in humans.

**Dosage and Administration:** 1 mg three times daily, one hour before meals, or 2 mg per day, taken one hour before lunch in a single dose.

**How Supplied:** Tablets, 1 mg and 2 mg, in packages of 100.

**Before prescribing or administering, see package circular for Prescribing Information.**

**MAZINDOL PHARMACEUTICALS, EAST MANOR, N.J. 07036**

## New US Role Offers Hope on Traffic Deaths

Continued from page 1

period in 50-50 matching grants for planning, implementation and research.

For the fiscal year ending June 30, 1974, the fund underwrote 88 projects for a total federal share of \$27 million.

For approval, grant applications must outline plans for EMS components covering both pre-hospital and post-hospital phases. Without the systems approach, EMS planning tended to be fragmented, according to Dr. Boyd.

"Most places just bought ambulances through the Department of Transportation without putting in the total program," he points out. "But, now, with our money, they can take on the total comprehensive package, including ambulances bought by DOT."

### Turning Point Seen

Although it's too soon for the projects to have made any headway, Dr. Boyd is confident the new federal role is a significant turning point. "I think this is what the country has been waiting for," he says. "It's the first time there's been a lead agency and a planned program built on patient care necessity. We've finally got someone up here where the buck stops. We've long had the expertise, the learning experience. Now we can transpose that."

Where to start is the question facing many communities. Some observers, pointing to the fact that at least half of all heart attack and accident victims die before they reach the hospital, argue that communications and transportation are the logical priorities. "If something isn't done in the first four minutes," notes Jerry Montgomery, Director of the EMS Division of Washington State's Kings County Department of Health, "it doesn't matter what the hospitals are like."

A federal demonstration project funded in 1972, is "lively on what happens in the street," according to Mr. Montgomery. "The first year we instituted EMS," he relates, "we were saving one of every ten victims. Then we added statewide community education and public instruction in cardiovascular resuscitation and the ratio went up to one in four. That's how effective attention to the pre-hospital phase can be."

### Pre-Hospital Phase Lags

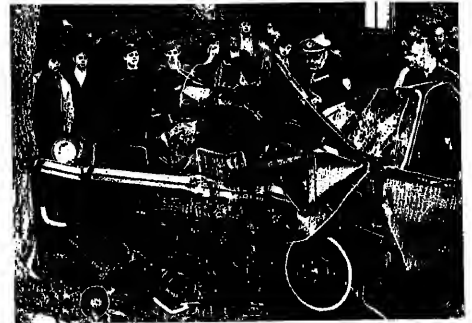
In Illinois, which has developed what is probably the most sophisticated state-wide EMS system in the country, the focus was on the hospitals and, as a result, the service still lags behind in the upgrading of the pre-hospital phase. In a much-publicized case that occurred in January, a pregnant woman died of a massive blood clot at a hospital just three blocks from her home when the local fire chief judged the situation a non-emergency and transferred the request for an ambulance to a fire department further away.

"We have to get them into the system sooner," emphasizes Blair L. Sadler, assistant vice president of the Robert Wood Johnson Foundation of Princeton, N.J., which in May announced 44 demonstration grants totaling \$15 million for projects with attention directed toward access, training of personnel and a central dispatch facility.

### 38 Frequencies Allocated

With the allocation by the Federal Communications Commission of 38 frequencies for emergency medical use under the EMS Systems Act, ambulance radio communication should improve, although many ambulances still lack radios.

Expensive telemetry monitoring systems which are being installed in many new EMS operations have made some experts uneasy, especially about their use in rural areas. "In order to support



That deaths from traffic accidents dropped in 1974 is attributed to the 55-mile speed limit rather than emergency medical services.

The issues involved in the design of a pre-hospital EMS system include:

• **Access.** Who does the citizen call when he needs emergency medical treatment? For economic, technical and political reasons, the 911 emergency number system has been adopted in only 20 per cent of the country. In Fairmont, West Virginia, the phone companies claim 911 implementation would take ten years at a cost of several million dollars.

Then there are those who think the value of the 911 system is over-rated. "People simply have to know who to call in their area," observes Dr. R. R. Hannas, Director of Emergency Services at Evanston Hospital in Evanston, Illinois. "It may be the fire department, the police, or the ambulance service, as long as the number is highly visible to the public."

• **Ambulances.** According to an HEW survey in mid-1971, 44 per cent of 25,000 ambulances in 37 states were operated by funeral homes. Dr. Boyd reckons that the figure hasn't changed much and may actually be as high as 50 per cent in rural areas. In tiny McCormick, South Carolina, with a population of 2,000, only a flashing red light on top of the vehicle distinguishes the ambulance from a hearse. "If they switch it off halfway to the hospital," reports a local physician, "you know what happened."

• **Communications.** Many systems have no central dispatch for ambulances. In Long Island's Suffolk County, first a police car is dispatched to the scene to decide whether an ambulance is necessary. If so, the car radios back to headquarters where in turn the preceptor is alerted. Finally, the preceptor calls the ambulance.

• **Training.** Although the American College of Surgeons and Department of Transportation designed a curriculum in 1969 for an 80-hour basic-level training program, providing certification as an Emergency Medical Technician (EMT), only about 25 per cent of the country's attendants have completed the training, and 7,000 of these are in Illinois.

• **Status of paramedic personnel.** The status of paramedic personnel—requiring an additional 120 hours of training—has been a major issue.

Continued on page 29



C I B A

## High-Risk Target Suggested In Urinary Tract Screening

Medical Tribune Report

SAN FRANCISCO—Which children are at risk for urinary tract infections? How can these infections be detected? And how should they be treated?

Dr. Patrick H. McLin, one of the speakers who discussed these questions at the annual meeting of the American Academy of Pediatrics here, described a mass screening program in which 86 of 13,148 children tested were found to be infected.

All were girls, said Dr. McLin, who estimated that 5 per cent of all girls will have trouble with urinary tract infections by the time of puberty.

The purpose of the screening, which was performed in the home by parents with a dip slide and sent back to schools for evaluation, was to determine morbidity as well as the incidence of actual or potential pyelonephritis. No pyelonephritis was detected.

Of those with infections, 44 per cent had a history of prior urinary tract disease, Dr. McLin reported. Forty per cent had symptoms of daytime wetting, frequency, urgency, or dysuria—indications that the infection was "hidden only because no one was watching."

### Many Unaware of Infections

Since many of the mothers were aware of the symptoms but not of the infections, an educational effort should be made to teach mothers what is abnormal, he suggested.

Of the 86 with infections three had reflux, but no evidence of scarring was found.

Dr. McLin put the screening cost at \$21,700, or about \$1.65 per child, not counting the cost of labor, which was volunteered. The cost per infection was approximately \$250—indicating that if mass screening is to be feasible, a target population should be defined, he said.

"This population should exclude boys and should include only high-risk girls in the kindergarten through sixth-grade age groups, he said. High-risk girls, he added, would include those with a high rate of absenteeism.

Dr. James E. Keeton of Jackson, Miss., said that urinary tract infections appear to be less frequent among black girls than among white and also less serious, with fewer abnormalities on intravenous pyelograms.

He also said that the incidence of reflux appears to be low and confined to preschool girls, with a high incidence of spontaneous resolution.

Dr. Joseph Y. Dwoskin of Buffalo, N.Y., observed that the infections seen by a pediatric urologist are usually more serious than those seen by a pediatrician since referrals are usually made only after two or more recurrences. The largest group of patients is in the three-to-four-year age range.

### Helmet Study Set

SAN ANTONIO, TEXAS—Southwest Research Institute here has been selected by the American Society for Testing and Materials to conduct a two-year study of football head and neck injury hazards with the aim of developing greater headgear protection.

he said, and 75 per cent are under seven years.

Unless the patients are on continuing antibiotic therapy, 50 to 65 per cent will have a recurrence within six months and 70 to 85 per cent within one year, he continued.

In one group with recurrent infections, 44 per cent had reflux and 25 per cent pyelonephritis, Dr. Dwoskin reported.

The incidence of reflux suggests that urethral manipulation should be part of the treatment for such patients, he remarked, and the incidence of pyelonephritis that investigation should be made earlier than usual. He suggested a workup after the first infection.

## 'At Home' Insight Into Heart Surgery Impact



Students from Stanford University Medical School visited a woman receiving from heart surgery "at home" recently for an insight into the impact that such an event has on patients and their families, emotionally and financially. Left to right: Leona McGinn, Assistant Professor; Julie Fay, student; Eddie Turner, former patient; John Sanchez, student; David Kuplin, Ph.D., director of clinical social work at Stanford; and Holly Stieglman, student.

## Space age microbicidal power BETADINE ANTISEPTICS

BETADINE Skin Cleanser and BETADINE Ointment provide the same broad-spectrum microbicidal action as BETADINE microbicides chosen by NASA for the Skylab mission and for Apollo 11, 12, 14 splashdowns. They kill gram-positive and gram-negative bacteria (including antibiotic-resistant strains), fungi, viruses, protozoa and yeasts... are virtually nonirritating and nonstaining... nonobnoxious to skin and natural fabrics.

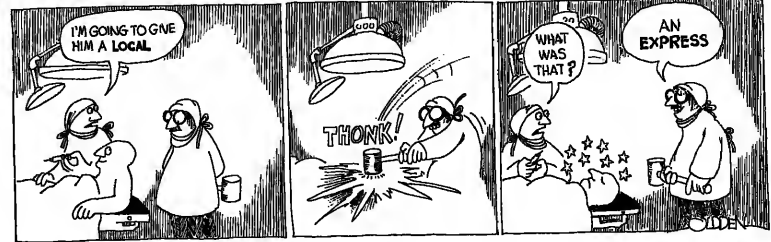
BETADINE Skin Cleanser dogers the skin of patients with common pathogens, including *Staph. aureus*... helps prevent recurrence of acute inflammatory skin infections and spread of infection in acne pimples... may be used routinely for general skin hygiene (in the two instances of local irritation or sensitivity, discontinue use in the individual).

BETADINE Ointment kills pathogens in skin and wound infections... indicated in infected stages ulcers and to help prevent infection in burns, lacerations and abrasions. Not greasy or sticky... the treated area can be bandaged.

Pouder Frederick



## Clinical Trials



## Doctors Slight Prevention Mission—Nader

Continued from page 1

1940s when physicians began saying that the best way to prevent highway-induced trauma is to design safer cars.

These pioneering reports eventually led to formation of Physicians for Automotive Safety, and a number of physicians are speaking out on the need to take action and mold public opinion, he agreed.

But Mr. Nader believes the profession in general has not organized itself to develop the new roles in preventive medicine for which physicians are "uniquely fitted" or to give those roles status and resources.

"Doctors who are crusaders are looked on in a pejorative way," he commented.

### 'Little Attention' to Pollutants

As an illustration of how the profession has "not taken the lead" in preventing illness and injury, Mr. Nader said that more and more research is being done on respiratory diseases in such areas as improvement of surgical techniques and retardation of spread, but "very little attention" is being paid to the epidemiologic role of industrial pollutants.

High on his list of "generic disease sources and generic trauma sources" are potentially harmful household products, equipment such as power lawn mowers, and such air and water contaminants as lead, mercury, synthetic industrial chemicals, and asbestos.

What action on the part of the medical profession does he recommend?

"This requires fundamental expansion of role conception so that hundreds if not thousands of physicians will be working in areas that have no relation to immediate treatment and diagnosis," Mr. Nader said.

### 'Physicians Without Patients'

"Physicians without patients are what we need in great numbers—physicians who would cooperate with other professional people like lawyers and engineers to try to redesign our technological environment to save life."

These physicians, he added, would work in public-health advocacy outside of government to make public-health efforts inside government "better than they are." They would also monitor government and corporate activities to see that established public-health policies are actually put into practice.

"The role of the physician in legislative conferences is probably more persuasive than that of any other pro-

MEDICAL TRIBUNE has campaigned since 1951 for highway safety, use of seat belts, and improved car design. Among the people honored by MEDICAL TRIBUNE for their efforts in the field of auto safety have been Dr. Fletcher D. Woodward, the Virginia ophthalmologist whose 1948 report on principles for reduction of deceleration injuries is considered a landmark; Dr. Horace E. Campbell, the Colorado surgeon who pressured manufacturers for better packaging of passengers; and Ralph Nader.

fession," Mr. Nader said. "Legislators listen when doctors testify."

Turning to traditional areas of concern, he predicted that the "major frontier of struggle" between medicine and the public over the next 10 or 15 years will encompass not only health insurance and availability of services but also cost control, quality control, preventive services, and consumer participation.

One hypothesis should be developed and either refuted or documented, Mr. Nader continued. Putting it in what he termed the "most provocative" fashion, he suggested debate on: "Resolved, there is more avoidable violence in America's hospitals than on America's streets."

### Outside Evaluation Urged

There is no ongoing institutional inquiry into the scope of avoidable hospital violence, he said, whether caused by neglect, inadequate supervision, communicable diseases, accidental electrocutions, unnecessary operations, malpractice, or misprescribing of drugs.

And he sees it as "near the level of the axiom" to conclude that no profession will be "even minimally responsible for its true duties unless it also has a system of evaluation outside of itself."

Look at lawyers "who have messed up our court system... and corrupted our political process," he suggested, or at architects responsible for New York structures "that look as if they were built by Con Edison."

So again Mr. Nader called for "public-interest-policy physicians and institutions" that would raise questions about allocation of the medical profession's resources, the profession's concern with both industrial and governmental policies, and participation of

the consumer in health insurance and health maintenance organizations.

### Bids Profession 'Tilt Its Axis'

"One would think that the profession would be willing to tilt itself to create a new dimension of its own operations—a public-interest dimension of 'physicians without patients,'" Mr. Nader said.

They would work, he summed up, in critical areas of "preventive medicine, health insurance, hospital practices, consumer protection laws." And they would "indicate into the area of technology assessment—assessing the consequences of technology long before something reaches the market."

Ralph Nader speaking at New York University School of Medicine.

## Psychiatric Drug Use Urged In Patients With Severe Burns

Medical Tribune World Service

PRAHUK—Pharmacotherapy should be included in the treatment of severe emotional disorders and psychiatric symptoms accompanying burns, according to Drs. Pavel Pavlovsky and Pavla Pokorna of the Psychiatric Research Laboratory of the Czechoslovak Academy of Sciences here.

Traumatizing changes in the patient's life produced by severe burns—feelings of self disgust and uselessness, doubts about the attitude of others, and even problems of accident compensation—represent such a degree of interference that neurotic disorders should be treated as serious psychic disturbances, they said.

Individual psychotherapy is often not sufficient, they maintained, and physician fear of side effects of pharmacotherapy is unwarranted.

Drs. Pavlovsky and Pokorna have used psychotherapeutic drugs in 245 of the 467 burns patients, whom they treated during hospitalization between 1967 and 1973. Their patients were seen twice a week for a period of five weeks, and evaluated for subjective somatic complaints, insomnia, and intensity of anxiety, and tested objectively for psychomotor rate, mood, psychologic signs, and attitude toward treatment.

Significant improvement in sleep disorders, subjective physical complaints, and anxiety moods was achieved in 78

patients, using daily doses of 10-40 mg. diazepam at intervals of one to eight days for an average of three weeks.

Chlorprothixene, used in 41 cases, had a more pronounced antidepressant effect, but this was not felt until the second week. The anxiolytic effect became apparent within the first two days, however, while the most conspicuous improvement was registered in sleep disorders. The drug was given in daily doses of 15-60 mg. for a period of from two to eight weeks.

### Other Drugs Used

Prothiaden, a Czech imipramine-like drug, was given in 12 cases of severe depression, in daily doses of 75 mg. for an average of three weeks, with improvement in all cases at the end of the second week.

Imipramine was tested in eight cases. In three of them improvement of the anaphrodisiac syndrome occurred at a daily dose of 75 mg. during the third week of administration.

Chlorpromazine in injections of from 50-100 mg. was found useful in cases of psychomotor unrest. Thioridazine was tolerated by elderly patients, but was not as effective in curbing psychomotor unrest in these cases as plegomazine. Occasional administration of psychomimetics did not produce significant change.

If there's good reason  
to prescribe  
for psychic tension...

Prompt action  
is a good reason  
to consider Valium®  
(diazepam)



When, for example, despite counseling,  
tension and anxiety continue to produce  
distressing somatic symptoms

When your patient's somatic complaints are associated with tension and anxiety and you have tried counseling and other supportive measures alone, you may decide to prescribe psychotherapeutic medication. If you do, the question remains: which one?

Valium (diazepam) is one to consider closely. One that works promptly as an adjunct to continued supportive measures. One that generally produces significant improvement within the first few days of therapy, although some patients may require more time for a clearcut response.

Prompt action. One good reason to consider Valium.

And should you choose to prescribe Valium, you should also keep this information in mind. Valium is usually well tolerated. Patients taking Valium should be cautioned against operating dangerous machinery or driving. Therapy with Valium should normally be continued until the patient's psychic tension symptoms have been reduced to tolerable levels.

Please turn page for a summary of product information.

**Valium®** ROCHE  
(diazepam)

2-mg, 5-mg, 10-mg tablets



# Valium® (diazepam)

Before prescribing, please consult complete product information, a summary of which follows:

**Indications:** Tension and anxiety states; somatic complaints which are concomitants of emotional factors; psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology, spasticity caused by upper motor neuron disorders, athetosis, stiff-man syndrome, convulsive disorders (not for sole therapy).

**Contraindicated:** Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

**Warnings:** Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anti-convulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms (similar to those with barbiturates and alcohol) have occurred following abrupt discontinuance (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence. In pregnancy, lactation or women of childbearing age, weigh potential benefit against possible hazard.

**Precautions:** If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed.

drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other anti-depressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or over-sedation.

**Side Effects:** Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

**Dosage:** Individualize for maximum beneficial effect. **Adults:** Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

**Supplied:** Valium® (diazepam) Tablets, 2 mg, 5 mg and 10 mg; bottles of 100 and 500. All strengths also available in Tel-E-Dose® packages of 100.

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Wednesday, February 5, 1973

MEDICAL TRIBUNE

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## Wrist Prosthesis Simulates Movement of Normal Joint

Medical Tribune Report

TUSCON, ARIZ.—A completely mobile wrist prosthesis of metal and plastic, which closely resembles the normal joint, has been designed and successfully implanted in two patients in a collaborative effort here by members of the Department of Surgery and Mechanical Engineering at the University of Arizona.

According to a preliminary report of the work by Dr. Robert G. Volz, orthopedic surgeon and Assistant Professor of Surgery at the university's College of Medicine, the replacement is not a ball-and-socket mechanism, which would cause unnatural movement, but half of a toroidal sector (shaped like a tire cut in half), fitted with an elliptical cup. Like the normal wrist, the combination allows for motion in two planes only—up-and-down (flexion extension) and side-to-side (radial and ulnar deviation).

### Appearance Called Excellent

The replacement gives an excellent cosmetic appearance if a deformity exists, and as much as 90° flexion extension and 50° deviation, the report said.

Clinical data is still incomplete, the Arizona team said, but the operation may be indicated for many patients with crushed or deformed wrists, and for persons with rheumatoid arthritis of the wrist without metacarpal, phalangeal, or interphalangeal involvement. The prosthesis would probably not be useful in replacing the wrist of an arthritic patient with appreciable hand or finger involvement.

One of the first patients to receive

the operation was a printer and part-time organist whose left hand was badly crushed in an accident. The two sections of the prosthesis were cemented to the radius on one end and the bones of the second and third fingers on the other. The metal portion is made of Vitallium, an alloy of cobalt chromium, which is not rejected by the body.

Both halves are held in place by methylmethacrylate. Three bones in the hand—the lunate, navicular and the head of the capitate—were resected to make room for the prosthesis. Unlike most other joints in the body, which must withstand mostly forces of compression, the wrist must be able to take forces of distraction as well—the tendency of the joint to be pulled apart when a suitcase is lifted, for example.

The Arizona team noted that patients have been able to lift a 40-pound suitcase and squeeze a ball tightly. Although clinical data is far from complete, the musician is already back at the organ, and the collaborative team is optimistic that the replacement will permit most normal life activity.

Because of the use of methyl methacrylate cement, which is used extensively in hip-joint replacements but rarely elsewhere, the University of Arizona group has had to obtain special permission from the FDA for each operation performed so far.

Assisting in the design of the prosthesis were Drs. Marvin D. Martin, Professor of Mechanical Engineering and Michael J. Pitt of the department of radiology. Mr. Richard Perry, a student in the Medical College, was also part of the team.

## 'Germfree' Helmet



Hospital personnel must wear special helmets in the University of Tennessee's "germfree" surgical suite designed for bone marrow surgery and total hip replacement. Dr. Lewis D. Anderson, Professor of Orthopedic Surgery, also uses the suite to study orthopedic aspects of sickle cell disease.

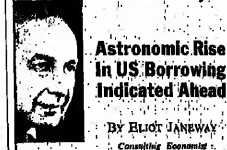
## Public Health Groups Urge Liberal Abortion in Israel

Medical Tribune World Service

TEL AVIV.—"Abortion on demand" was urged here recently by the National Society of Public Health and the Society of Public Health Physicians at a joint meeting.

Disappointment was voiced that a proposed abortion law, now pending in the Knesset, Israel's Parliament, provided that committees would be set up to consider requests for abortion. Several speakers pointed out that this favored the rich and well-to-do.

## Tribune Economic Analysis



### Astronomic Rise in US Borrowing Indicated Ahead

BY ELIOT JANEWAY  
Consulting Economist

All the various "dos" under consideration as remedies for the present disaster of accelerating slump and continuing inflation cost money. But even if the bottom were not falling out of the economy, only one way of finding new money would be open to the government: borrowing still more.

As matters stand, the collapse in commitment-making is forcing a companion collapse in revenue collections. Higher levels of spending, against lower levels for collections and higher levels for refunds, point to escalations in federal borrowings of astronomic proportions.

The most massive federal pump priming for housing will not be sufficient as long as the cost level of fueling and financing buildings is prohibitively higher than the income level of rents and as long as the required level of rents is prohibitively higher than the proportion of family budgets available to pay them.

Despite brave talk of keeping Federal disbursements down to \$300 billion a year, they are headed closer to \$400 billion.

Government actions calling for Treasury borrowing are bound to send the economy on a collision course with the money markets. Interest rates are now conditioned to rise with government needs for money. The shock of absorbing higher interest rates just when the collapse of the economy is signaling the need for bargains in borrowing costs would finish off the wounded securities markets.

Are auto prices going to be forced down? I say yes. How else are they going to unload them. But what do you say?

Dr. E. E., Chicago

Yes, they will. But there's many a slip between price cutting and unloading. Ford has taken the lead by marking the Pinto down, but with no results as yet. The trouble goes back to 1973's phony boom. So euphoric was the industry's mismanagement that it failed to realize it was doing three years' business in one. I would caution against oversimplifying. Detroit's mismanagement has left dealers loaded with small cars no one wants, but short of higher priced cars.

Can we expect an upturn by fall? If so, what will be the factors that will bring it about?

Dr. Frederick W., New York

Not if the government continues to sit around and wait for it. But if Ford begins to act like a President and overrules Kissinger's veto or a confrontation, an upturn would follow within weeks after U.S. political initiatives knock the price of oil down. There's no way out short of using political muscle to knock down the price of fuel and with it the cost of money.

## New US Role Offers Hope on Traffic Deaths

Continued from page 21

training in life support techniques including cardiopulmonary resuscitation, defibrillation, administration of drugs and intravenous fluids—is in even greater limbo. In Illinois, the 460 paramedics are operational mainly in the Chicago area, only in those communities that can afford to fund them as part of the telemetry program. Yet, many observers feel that it is the rural areas that really need paramedics, although they are concerned whether the occasional use of these specialized skills is sufficient to maintain proficiency.

● Absence of medical leadership. "In Illinois I was it," says Dr. Boyd who deplores what he considers a crucial lack of doctors at the forefront of EMS development. "It's one thing to have a doctor from the medical society on the advisory committee," he says briskly, "and quite another to find an active leader."

Dr. Bill Henry, a family practitioner in rural Twisp Washington, seconds Boyd's complaint. "EMS development is being done by fire departments and Comprehensive Health Planning agencies, completely outside the control of physicians because of their abnegation and refusal to take any responsibility," he criticizes. "I can identify four physicians out of 125 in my area who are actively involved. I don't see how you can have a successful EMS system without some input from the guys doing the blood and guts work."

When Dr. Henry came to Twisp four years ago, he was confronted with a frontier-town brand of EMS. "When there was an emergency," he recalls, "I used to go into the bar and pick out the guys who looked best and then get the water maintenance truck."

### Trained 30 Technicians

After two people died unnecessarily, Henry began to turn things around. First, he garnered some money and then bought two ambulances, one equipped with telemetry. He trained 30 emergency medical technicians, (EMTs) setting up a special mountain rescue squad who parachute into the mountains, start IVs, and clear heliports so Dr. Henry can land by helicopter.

"I train them in the ER and even when they set broken bones," he explains. "This is the kind of exposure they need to be adequate EMTs. But big hospitals are too scared liability-wise to have them in there."

Another E.P. who has played a leadership role is Dr. Richard Ladenheim from Anna, Illinois. "When the

trauma coordinator went into the community and tried to find a doctor to teach EMTs," he remembers, "I was the only one willing to do it. F.P.s hate traumatic work in any form or fashion. They don't feel qualified and they're always worrying about lawsuits. The only ones who take special training in emergency medicine are the ones who don't need it."

In a unique approach to solving the problem of ambulance service for rural Illinois Johnson and Pope Counties, Dr. Ladenheim lent his support to a controversial plan to train inmates at the minimum-security Vienna Correctional Institution to provide the 11,500 people of the area with 24-hour coverage. So far, 200 men have been trained. Age 18, 200 men have been trained. Age 18, 200 men have been trained. Age 18, 200 men have been trained.

The plan calls for the inmates to continue working in the area once they are discharged. "There's a lot of racial tension in this area," observes Dr. Ladenheim. "To suddenly ask people to take in not only blacks but black inmates is going to take a lot of public education. Each doctor is going to have to talk to his patients as they come in. Of course, once John Jones says 'they saved my life', everything will be okay."



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